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No Question / Answer Code Stop to Stop to Stop to Stop to Stop to Stop to PROBE F ULL.Y Recombinant vs human plas ma-derived 1 Well-established/stand and produce 2 Albuminr/protein content 3 Efficacy/response rates 4 Duration of eff sct/half life 5 Speed of resp mse/effect 6 Safety (u specified) 7 Lack of advers - reactions Lack of album in reaction 9 Lack of viral) con amination 0 Lack of immunity/resistance/lack of inhibitor de relopment X Range of potences/vial sizes V Diluent/infusion volume 1 Storage (refrigeration vs room temperature) 2 Shelf-life 3 Supply/availability 4 Delivery to pate nt's home 5 Manufacturer (e g reputation/involvement in haemophilia) 6 Good) relationship with the mar ufacturer 8 Speed of reconstitution 9 Ease of administration 0 Cost (14) (15) (16)			(T)-(2) 05	(3)-(11)
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Cost X (14) (15) (16) (17)		Speed of reconstitution	9	
(14) (15) (16) (17)		Ease of administration	0	
(15) (16) (17)		Cost		1
(16)			(14)	
(17)			(15)	
i i			(16)	1
i i			(17)	†
	-	Other (please specify)		
				•
Do n't know V		Do n't know	v	

Vo		Question / Answer	Code	S- : :
29	How satisfied are you with the products? Would you say you	currently available recombinant Factor VIII		
	SHOW CARD 1		(18)	1
		Very dissatisfied	1	
	ļ	Fairly dissatisfied	2	•
		Neither satisfied nor dissatisfied	3	
		Fairly satisfied	4	
		Very satisfied	5	1
		Don't know	V	
210	What improvements would yo products?	u like to see made to recombinant Factor VIII	(19)	
•	PROBE FULLY	Reduced use of albumin/protein	1	
		Improved efficacy/response	2	
		Longer lasting effect/longer half-life	3	
		Improved speed of response/effect	4	
		Improved safety (unspecified)	5	
		Fewer adverse reactions	6	
		Reduced/no albumin reaction	7	
		Reduced/no (viral) contamination	8	
	Red	uced immunity/resistance/inhibitor development	9	
		Higher potencies/larger vial sizes	0	
			(20)	
		Reduced volume of diluent/infusion	•	
		Indication for continuous infusion	2	•
		Improved storage (refingeration not required)	3	
		Longer shelf-lite	4	
		Improved supply/availability	5	
		Clearer storage instructions	6	
	Improv	ed packaging/less wastage of ancillary products	7	
		Improved/easier reconstitution	8	
		Faster reconstitution	9	
		Improved/easier administration	0	
	·	Reduced cost	(21)	
			(21)	
			(22) (23)	_
			(24)	
		Other (please specify)	X	
	****************	. Don't know	v	

No	Outsides / Assessed	Code	
140	Question / Answer HAND DOCTOR SHOW CARD A		Skip to
	THIS CARD LISTS SEVERAL FEATURES ON WHICH POTENTIAL NEW RECOMBINANT PRODUCTS FOR HAEMOPHILIA A MIGHT CIFFER PLEASE TAKE A FEW MINUTES TO READ OVER THE FEATURES AND THEIR VARIOUS LEVELS, AS THIS INFORMATION WILL MAKE THE FOLLOVING EXERCISE RUN MORE SMOOTHLY		
	ALLOW RESPONDENT TIME TO READ ALL INFORMATION OF THE CARD		
	I HAVE HERE 32 CARDS, EACH DESCRIBING A POTENTIAL RECOMBINANT FACTOR VIII PRODUCT WITH A UNIQUE COMBINATION OF FEATURES NO TWO CARDS ARE EXACTLY THE SAME FOR THE PURPOSE OF THIS EXERCISE, PLEASE IMAGINE THAT THESE 32 POTENTIAL PRODUCTS ARE THE ONLY ONES AVAILABLE FOR THE TREATMENT OF HAEMOPHILIA A		
	HAND DOCTOR SHUFFLED CARDS	-	
	CONSIDERING YOUR PATIENTS WITH HAEMOPHILIA A, PLEASE SORT THESE 32 POTENTIAL PRODUCTS INTO 3 PILES ACCORDING TO YOUR LIKELIHOOD TO PRESCRIBE THEM ONE PILE SHOULD CONTAIN THOSE PRODUCTS THAT YOU WOULD BE MOST LIKELY TO USE, ONE THOSE PRODUCTS THAT YOU MIGHT CONSIDER USING AND ONE THOSE PRODUCTS THAT YOU WOULD BE LEAST LIKELY TO USE "OU CAN HAVE ANY NUMBER OF CARDS IN EACH OF THE 3 PILES		·
	ASSUME THESE PRODUCTS ARE EQUAL ON ANY FEATURES "HAT ARE NOT INCLUDED ON THE CARDS		
	THIS IS A VERY IMPORTANT PART OF THE STUDY PLEASE TAKE YOUR TIME AS WE REALISE THIS TASK REQUIRES CAREFUL CONSIDERATION		
	WAIT UNTIL THE DOCTOR HAS SORTED ALL THE CARDS INTO THREE PILES, THEN CONTINUE		
	I WOULD NOW LIKE YOU TO RANK THESE 32 CARDS FROM TOP TO BOTTOM, STARTING WITH THE PRODUCT YOU ARE MOST LIKELY TO PRESCRIBE FOR HAEMOPHILIA A ON THE TOP, THROUGH TO THE PRODUCT YOU ARE LEAST LIKELY TO PRESCRIBE ON THE BOTTOM		
	PLEASE BEGIN BY RANKING THESE PRODUCTS IN THE "MOST L'KELY" PILE		
	AFTER "MOST LIKELY" PILE IS RANKED, ASK THE DOCTOR 'O CONTINUE WITH THE PILE OF PRODUCTS HE/SHE "MIGHT PRESCRIBE" AND THEN FINALLY RANK THE "LEAST LIKELY" PILE.		
	ONCE THE DOCTOR HAS FINISHED SAY		
	PLEASE READ OUT THE NUMBERS OF THE CARDS IN THE ORDER YOU HAVE ARRANGED THEM THE FIRST NUMBER YOU READ OUT SHOULD BE THE PRODUCT YOU ARE MOST LIKELY TO PRESCRIBE AND THE LAST NUMBER YOU READ OUT SHOULD BE THE PRODUCT YOU ARE LEAST LIKELY TO PRESCRIBE	•	
	RECORD RESPONSES ON NEXT PAGE		

(11-2	3 —
CS	BEDEAT

RANK	PRODUCT CARD NUMBER	RANK	PRODUCT CARD NUMBER
	(12) (13)		(44) (45)
1 (MOST LIKELY)		17	
	(14) (15)		(46) 4
2		18	
	(16) (17)		(48) (49)
. 3		19	
	(18) (19)		(50) (51)
4		20	
•	(20) (21)	20	(52) 53
	(20) (21)		(32) 33
5		21	
	(22) (23)		(54) (55)
6		22	
•	(24) (25)		(56) (57)
7		23	
	(26) (27)		(58) (59
. 8	·	24	(
1	(28) (29)		(60) 61,
9 ်		25	
	(30) (31)		(62) 53'
10		26	
	(32) (33)	-	′64) 55 [\]
11		27	
	(34) (35)		(66) (67)
40		00	
12		28	<u></u>
	(36) (37)		(68) 69
13		29	
	(38) (39)		(70) (74)
14		30	
	(40) (41)		(72) (73)
15		31	
	(42) (43)		(74, - 75
16		32 (LEAST LIKELY)	
	L1	~	

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		(1)-(2)	(3)-(11) REPEAT
No	Question / Answer	Code	Skip to
Q11	Considering the potential product that you ranked as the one you would be most interested in using, what are your reasons for ranking it first? PROBE FULLY		
		(12)	
		(13)	
		(14)	
Q12	Considering the potential product that you ranked as the one you would be most likely to use, how interested would you be in using it in the harmophilia A patients treated at this centre? Would you say you were SHOW CARD 2	(15)	
	Not at all interested	(15)	
	Not very interested	2	
	Neither interested nor disinterested	3	
	Fairly interested	4	
	Very interested	5	ľ
	Don't know	. v	
Q13	Considering the potential product that you ranked as the one you would be most likely to use, would you be willing to advocate paying a price premium for that product?	(16)	
	Yes	1	Q14
	No	2	THANK
	Don't know	٧	CLOSE
Q14	What percentage price increase over currently available recombinant products would you consider to be acceptable?		
	(17) (18) (19)	(20)	
	% Depends	Х	Q15
	enter percentage Dor't know GO TO Q16 IF 'DEPENDS', OTHERWISE THANK AND CLOSE	٧	THANK AND CLOSE

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No	Question / Answer	Ccae	Sep o
Q15	On what would the acceptable level of price increase depend? PROBE FULLY		
		(21)	
		(22)	7
		(23,	

THANK AND CLOSE

CARD A

Doctors

Human or animal derived protein

- > used in manufacturing (culturing) and in the final formulation (for stabilising)
- > used in manufacturing (culturing), but not in the final formulation (for stabilising)
- > not used at all

Continuous infusion

- > an approved indication
- > product has capability, but not approved (label indication)
- > not possible (to be used for continuous infusion)

Diluent volume per vial

- > 25ml
- > 5mi
- > 10ml

Higher number of activity units per vial

- > 1,000 ı u per viai
- > 1,250 i u per vial
- > 1,500 ru per vial
- > 2,000 i u perviai

Assay issue

- > requires one-stage assay
- > requires chromogenic assay (not available in every hospital)

Room temperature storage

- > Cannot be stored at room temperature (requires refrigeration)
- > 3 months
- > 6 months
- > 1 year
- > 2+ years

rFVIII molecule

- > full length
- > B-domain deleted

DOCTOR - CARD 1

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stabilising)

Continuous infusion

> an approved indication

Diluent volume per vial

> 5⊓1

Higher number of activity units per vial

> 1,250 i u per vial

Assay issue

> requires one-stage assay

Room temperature storage

> 6 months

rFVIII molecule

DOCTOR - CARD 2

Human or animal derived protein

> used in manufacturing (culturing) and in the final formulation (for star! sing:

Continuous infusion

> an approved indication

Diluent volume per vial

> 5ml

Higher number of activity units per vial

> 1,000 iu pervial

Assay issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage
➤ 3 months

rFVIII molecule

DOCTOR - CARD 3

Human or animal derived protein

➤ not used at all

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial
➤ 5ml

Higher number of activity units per vial > 1,500 i u per vial

Assay issue

> requires one-stage assay

Room temperature storage > 2+ years

rFVIII molecule

DOCTOR - CARD 4

•
Human or anımal derived protein ➤ not used at all
Continuous infusion > not possible (to be used for continuous infusion)
Diluent volume per vial > 5ml
Higher number of activity units per vial > 2,000 i u per vial
Assay issue > requires chromogenic assay (not available in every hospital)
Room temperature storage > Cannot be stored at room temperature (requires refingeration)
FVIII molecule ➤ B-domain deleted
·

DOCTOR - CARD 5

Human or animal derived protein

➤ not used at all

Continuous infusion

> product has capability, but not approved (label indication)

Diluent volume per vial

> 10ml

Higher number of activity units per vial

> 1,250 i u per vial

Assay Issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage

⇒ 3 months

rFVIII molecule

DOCTOR - CARD 6

Human or animal derived protein

➤ not used at all

Continuous infusion

> product has capability, but not approved (label indication)

Diluent volume per vial

➤ 10ml

Higher number of activity units per vial

> 1,000 ru per vial

Assay Issue

> requires one-stage assay

Room temperature storage
➤ 6 months

rFVIII molecule

DOCTOR - CARD 7

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stabilising)

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 10ml

Higher number of activity units per vial

> 1,500 ru per vial

Assay issue

> requires chromogenic assay (not available in even hospital)

Room temperature storage

> Cannot be stored at room temperature (requires refigeration)

rFVIII molecule

DOCTOR - CARD 8

Human or animal derived protein

> used in manufacturing (culturing) and in the final formulation (for stabilising)

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 10ml

Higher number of activity units per vial

> 2,000 iu pervial

Assay issue

> requires one-stage assay

Room temperature storage

> 2+ years

rFVIII molecule

DOCTOR - CARD 9

Human or animal derived protein

> used n manufacturing (culturing) and in the final formulation (for stabilising)

Continuous infusion

> an approved indication

Diluent volume per vial
> 2 5ml

Higher number of activity units per vial

> 1,250 au per vial

Assay Issue

> requires one-stage assay

Room temperature storage

> Cannot be stored at room temperature (requires refingeration)

rFVIII molecule

DOCTOR - CARD 10

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stabilising)

Continuous infusion

> an approved indication

Diluent volume per vial

> 25ml

Higher number of activity units per vial

> 1,000 iu pervial

Assay Issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage

≥ 2+ years

rFVIII molecule

DOCTOR - CARD 11

Human or animal derived protein

➤ not used at all

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

➤ 25ml

Higher number of activity units per vial > 1,500 ι u per vial

Assay issue

> requires one-stage assay

Room temperature storage
➤ 3 months

rFVIII molecule

➤ full length

DOCTOR - CARD 12

Human or animal derived protein

➤ not used at all

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 2 5ml

Higher number of activity units per vial > 2,000 i u per vial

Assay issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage
➤ 6 months

rFVIII molecule

DOCTOR - CARD 13

Human or animal derived protein

➤ not used at all

Continuous infusion

> product has capability, but not approved (label incication)

Diluent volume per vial

> 10ml

Higher number of activity units per vial

> 1,250 i u per vial

Assay issue

> requires chromogenic assay (not available in ever / hospital)

Room temperature storage > 2₁ years

rFVIII molecule

DOCTOR - CARD 14

Human or animal derived protein

➤ not used at all

Continuous infusion

> product has capability, but not approved (label indication)

Diluent volume per vial

> 10ml

Higher number of activity units per vial > 1,000 i u per vial

Assay issue

> requires one-stage assay

Room temperature storage

➤ Cannot be stored at room temperature (requires refingeration)

rFVIII molecule

DOCTOR - CARD 15

Human or animal derived protein

> used in manufacturing (culturing) and in the final formulation (for stabilising)

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 10ml

Higher number of activity units per vial

> 1,500 ru per vial

Assay issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage

> 6 months

rFVIII molecule

DOCTOR - CARD 16

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stabilising)

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 10ml

Higher number of activity units per vial

> 2,000 i u per vial

Assay Issue

> requires one-stage assay

Room temperature storage
➤ 3 months

rFVII molecule

DOCTOR - CARD 17

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stabilising)

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 10ml

Higher number of activity units per vial

> 1,000 ru per vial

Assay issue

> requires chromogenic assay (not available in even hospital)

Room temperature storage

⇒ 1 year

rFVII molecule

DOCTOR - CARD 18

Human or animal derived protein

> used in manufacturing (culturing) and in the final formulation (for stabilising)

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 10ml

Higher number of activity units per vial

> 1,250 i u per vial

Assay issue

> requires one-stage assay

Room temperature storage

> 3 months

rFVIII molecule

DOCTOR - CARD 19

Human or animal derived protein

➤ not used at all

Continuous infusion

> an approved indication

Diluent volume per vial > 10mi

Higher number of activity units per vial > 2,000 i u per vial

Assay Issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage > 2+ years

rFVIII molecule

> full length

DOCTOR - CARD 20

Human or animal derived protein

➤ not used at all

Continuous infusion

> an approved indication

Diluent volume per vial
➤ 10ml

Higher number of activity units per vial > 1,500 i u per vial

Assay Issue

> requires one-stage assay

Room temperature storage

> Cannot be stored at room temperature (requires refingeration)

rFVIII molecule

DOCTOR - CARD 21

Human or animal derived protein

➤ riot used at all

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 5ml

Higher number of activity units per vial > 1,000 i u per vial

Assay Issue

> requires one-stage assay

Room temperature storage

> 3 months

rFVIII molecule

DOCTOR - CARD 22

Human or animal derived protein > not used at all

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 5ml

Higher number of activity units per vial > 1,250 i u per vial

Assay issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage

▶ 1 year

rFVIII molecule

DOCTOR - CARD 23

Human or animal derived protein > used in manufacturing (culturing), but not in the final formulation (for stabilising) Continuous infusion > product has capability, but not approved (label incication) Diluent volume per vial > 5ml Higher number of activity units per vial ➤ 2,000 i u per vial Assay issue > requires one-stage assay Room temperature storage > Cannot be stored at room temperature (requires refingeration) rFVIII molecule > full length

DOCTOR - CARD 24

Human or animal derived protein

> used in manufacturing (culturing) and in the final formulation (for stabilising)

Continuous infusion

> product has capability but not approved (label indication)

Diluent volume per vial

> 5ml

Higher number of activity units per vial

> 1,500 i u per vial

Assay issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage

≥ 2+ years

rFVIII molecule

DOCTOR - CARD 25

Human or animal derived protein

> used in manufacturing (culturing) and in the final formulation (for stabilising)

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 10ml

Higher number of activity units per vial

> 1,000 i u per vial

Assay Issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage

> Cannot be stored at room temperature (requires re ngeration)

rFVIII molecule

DOCTOR - CARD 26

Human or anımal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stabilising)

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 10ml

Higher number of activity units per vial

> 1,250 i u per vial

Assay issue

> requires one-stage assay

Room temperature storage

> 2+ years

rFVIII molecule

DOCTOR - CARD 27

Human or animal derived protein

➤ not used at all

Continuous infusion

➤ an approved indication

Diluent volume per vial
10ml

Higher number of activity units per vial > 2,000 i u per vial

Assay issue

> requires chromogenic assay (not available in even nospital)

Room temperature storage

➤ 3 months

rFVIII molecule

➤ full length

DOCTOR - CARD 28

Human or animal derived protein > not used at all

Continuous infusion

> an approved indication

Diluent volume per vial > 10ml

Higher number of activity units per vial ➤ 1,500 i u per vial

Assay Issue

> requires one-stage assay

Room temperature storage

→ 1 year

rFVIII molecule

DOCTOR - CARD 29

Human or animal derived protein

➤ not used at all

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 2 5ml

Higher number of activity units per vial > 1,000 i u per vial

Assay Issue

> requires one-stage assay

Room temperature storage
> 2+ years

rFVIII molecule

➤ full length

DOCTOR - CARD 30

Human or animal derived protein

> not used at all

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial > 2.5ml

Higher number of activity units per vial

> 1,250 i.u per vial

Assay Issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage

> Cannot be stored at room temperature (requires refingeration)

rFVIII molecule

> B-domain deleted

DOCTOR - CARD 31

Human or animal derived protein

> used in manufacturing (culturing) and in the final ormulation (for stabilising)

Continuous infusion

> product has capability, but not approved (label indication)

Diluent volume per vial

> 2.5ml

Higher number of activity units per vial

> 2,000 i u per vial

Assay issue

> requires one-stage assay

Room temperature storage
➤ 1 year

rFVIII molecule

> full length

DOCTOR - CARD 32

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stabilising

Continuous infusion

> product has capability but not approved (label indication)

Diluent volume per vial > 25ml

Higher number of activity units per vial > 1,500 i u per vial

Assay Issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage
➤ 3 months

rFVIII molecule

> B-domain deleted

Appendix I

(b) Nurses

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CC	V No	Country	Senai	Nur

INTERNATIONAL HEALTH SURVEYS, LUDGATE HOUSE, 245 BLACKFRIARS ROAD, LONDON SEI 9UL

RECOMBINANT FVIII POSITIONING STUDY NURSE SCREENING QUESTIONNAIRE

Nurse name	audocatalicooppostototototototototototototototototo
Centre name	#
Address	
(please print)	***************************************

Telephone No	***************************************

INTRODUCTION

GOOD MORNING/AFTERNOON MY NAME IS FROM INTERNATIONAL HEALTH SURVEYS, AN INDEPENDENT MARKET RESEARCH AGENCY BASED IN LONDON, WHICH SPECIALISE IN CONDUCTING SURVEYS AMONG MEMBERS OF THE MEDICAL PROFESSION AND PATIENTS

WE ARE CURRENTLY CONDUCTING AN INTERNATIONAL STUDY W'TH DOCTORS, NURSES AND PATIENTS ON THE SUBJECT OF HAEMOPHILIA A.

THE INTERVIEW WILL LAST UP TO 45 MINUTES THE INFORMATION YOU PROVIDE WILL BE COMBINED WITH THAT OF YOUR COLLEAGUES NEITHER YOUR IDENTIFY NOF THAT OF YOUR HOSPITAL WILL BE REVEALED TO ANY THIRD PARTY STRICT CONFIDENTIALITY IS ASSURED

WOULD YOU BE WILLING TO TAKE PART IN OUR SURVEY?

COULD I FIRST ASK YOU A FEW QUESTIONS TO ASSESS YOUR ELIGIBILITY FOR THIS SURVEY

No	Question / Answer	Code	Sk.p to
Q1	Do you work at/are you affiliated with a specialist/comprehensive haemophilia treatment centre?	(12)	
	Yes	1	CONTINUE
	No	2	THANK AND
,	Dor't know	V	CLOSE
Q2	Do you specialise in the treatment of haemophilia/bleeding disorders?	(13)	
	Yes	1	CONTINUE
	No	2	THANK AND
	Dor't know	V	CLOSE

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No	Question / Answer	Code	Skpc
QЗ	Are you involved in the treatment of haemophilia A?	(14)]
	Yes	1	CONTINUE
	No	2	THANK AND
	Don't know	V	C_OSE
Q4	Are you regularly involved in the reconstitution and administration of recombinant Factor VIII products for treating haemophilia A?	(15)	
	Yes	1	RECPUIT
•	No	2	CNA MAAHT
	Don't know	V	CLOSE

version 3 (Final) 23rd November 1999

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INTERNATIONAL HEALTH SURVEYS, LUDGATE HOUSE, 245 BLACKFRIARS ROAD, LONDON SE1 9UL

RECOMBINANT FACTOR VIII POSITIONING STUDY NURSE QUESTIONNAIRE - EUROPE

NAME CENTRE NAME. ADDRESS			(PRINT) (PRINT) (PRINT)	
POST CODE TEL NO			(PRINT)	
YEAR OF QUALIFICAT	TON	TYPE OF HOSPITAL	(15)	
(12)	(13)	Publi:	1	
1 9		Рпуа е	2	
			(16)	
REGION (UK VERSION	i) (14)	Teaching	1	
Northern & Yorkshire	1	Non-teaching	2	
Trent	2			
North West	3	HOSPITAL BED SIZE		
West Midlands	4	(17) (18) (1	9) (20)	
Anglia & Oxford	5			
South & West	6		(21)	
North Thames	7	Don't know	V	
South Thames	8			
Wales	9			
Scotland	0			
Northern Ireland	×			
		COLUMNS (22)-(8	64) BLANK	
TIME STARTED	DATE OF INTERVIEW	(65) (66) (67) (68) (69) (70)	(71) (72) (73) (74)	
TIME FINISHED	INTERVIEWED BY		(75) (76) (77) (78) (79)	
RESPONDEN	OU NT SIGNATURE FOR FEE.	(14) Teaching 1 1 Non-teaching 2 2 3 HOSFITAL BED SIZE 4 (17) (18) (19) (20) 5 (21) 7 Don't know V 8 9 0 X COLUMNS (22)-(64) BLANK DATE OF INTERVIEW (65) (66) (67 (68) (69) (70) (71) (72) (73) (74) (79) INTERVIEWED BY (75) (75) (77) (78) (79) OUO (80) 1 2 3 4 5 6 7 8 9 0 X V ATURE FOR FEE. INTERVIEWER SIGNATURE.		
THIS INTERVIEW I	(signature) HAS BEEN CONDUCTED WITHIN THE T	(signature) TERMS OUTLINED BYTHE MRS CODE	OF CONDUCT	

	· · · · · · · · · · · · · · · · · · ·	(1)-(2)	3-11
-		10	255 ⁻
No	Question / Answer	Code	Sko o
Q1	Approximately how many haemophilia patients in total are treated at this centre?		
			i
1	(12) (13) (14)		
İ		(*5,	
ļ	Don't know	٧	
			<u> </u>
Q2	Of all haemophilia patients treated at this centre, what percentage have		1
	haemophilia A and what percentage have haemophilia B?		
	i) Haemophilia A		
	(16) (17) (18)		
	(10) (17) (10)	(43.	
		(19)	
	Don't know	V	
	ii) Haemophilia B	7	
	(20) (21) (22)	(23)	•
	None	0	
	Don't know	V	
	RESPONDENT MUST HAVE HAEMOPHILIA A PATIENTS (SEE SCREENER)		
	ENSURE TOTAL EQUALS 100%		
		,	
	EXPLAIN TO THE RESPONDENT THAT THE REST OF THE		
	QUESTIONNAIRE CONCENTRATES EXCLUSIVELY ON HAEMOPHILIA A		
Q3	Thinking of all the haemophilia A patients treated at this centre, what percentage		
ļ	are adults and what percentage are paediatrics?		
	i) Adults		
,	(24) (25) (26)	127,	
	None	0	•
	Don't know	٧	
	ii) Paediatrics		1
	(28) (29) (30)	(31)	1
	% None	0	,
	Don't know	٧	
	ENSURE TOTAL EQUALS 100%		
	<u> </u>		

Case 1:01-cv-12257-PBS Document 6866-20 Filed 01/27/10 Page 47 of 150 No Question / Answer Code Skip to Q4 NOT TO BE ASKED IN EUROPE COLUMNS (32)-(43) BLANK **Q**5 Thinking of all the haemophilia A patients treated at this centre, what percentage currently use recombinant Factor VIII products and what percentage use human plasma denved Factor VIII products? i) Recombinant (45)(47)Don't know ٧ ii) Human plasma (49)(50)(51)None 0 Jon't know RESPONDENT MUST HAVE PATIENTS ON RECOMBINANT PRODUCTS (SEE SCREENER) **ENSURE TOTAL EQUALS 100%** Q6 NOT TO BE ASKED IN EUROPE **COLUMNS (52)-(55) BLANK Q7** Typically on how many occasions per week do you reconstitute/adm nister recombinant Factor VIII products? occasions per week (59)E on't know RESPONDENT MUST BE INVOLVED IN THE RECONSTITUTION

ADMINISTRATION OF RECOMBINANT PRODUCTS (SEE SCREEVER)

		į	<u>(1)-</u> ;		3=
No	Qu	estion / Answer		Cose	Sep o
Q8a	Which specific brands of Factor VIII	products are currently used in patients at this	S j	-	
	centre (both recombinant and humai	n plasma derived products)?	- 1		1
28b	NOT TO BE ASKED IN EUROPE	·			
AVN	Hollo Bulletone hamolica	·			
	i		;		
			1		
		Q8a			
		Usage			}
	Recombinant	-			
	}	(12)			
	Bioclate	1			
	Helixate	2			
	Kogenate	3	•		
	Recombinate	4			
	Refacto	5			
	<u>Human plasma</u>	(13)	1		
	Alphanate	1			!
	Benate	2			
	Contact F	3	ł		
	Crosseight M	4			
	Emoclot Fhandi	5 6			
	Haemate-P/Humate P	7			
	Haemoctin	8			
	Hemofil M	9			
	knmunate	0			
	Innobrand	X			
	Koate DVI	V	;		
	1	(14)			
	Kryobulin	1			
	Monarc M	2			
	Monoclate-P	3			
	Nordiate	4			
	Octenate	5	,		
	Octinativ M	6			
	Profilate	7			
	Replenate	8			
	Uman	9			
]	(15)	,		
	Other (specify)	X			
			1		I
			1		1
		COLUMNS (16)-(76) BL	ANK !		l
		COLONINO (10)-(10) BL	. 411		ī

		(1)-(2)	(3)-(11)
		12	REPEAT
No	Question / Answer	Code	Skip to
Q9	What factors influence the choice of Factor VIII treatment for haemophilia A patients?		
	PROBE FULLY	(12)	1
	Recombinant vs human plasma-derived	1	
	Well-established/standa d product	2	
	Albumin/protein content	3	
	Efficacy/response rates	4	
	Duration of effect/half life	5	
	Speed of response/effect	6 .]
	Safety (unspecified)	7	
	Lack of adverse reactions	8	
	Lack of albuming reaction	9	1
	Lack of (viral) contamination	0	,
	Lack of immunity/resistance/lack of inhibitor development	x	
	Range of potencies/vial sizes	٧	
		(13)	
	Diluent/infusion volume	1	
	Storage (refingeration vs room temperature)	2	1
	Shelf-life (3	
	Supply/availability	4	
	Delivery to patier t's home	5	
	Manufacturer (e g reputation/involvement in haemophilia)	6	
	(Good) relationship with the man ifacturer	7	
	Ease of reconstitution	8	
	Speed of reconstitution	9	
	Ease of admir istration	0	
	Cost	X	_
		(14)	
		(15)	
		(16)	
		(17)	
	Other (please specify)	х	

	Dor't know	٧	

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- Case U1-CV-1//5/-P65 DC	ucumem papp-zu	FIREG UTIZATIO	Page 50 Or	コンロ
Occording to the second	OUGHINOIN GOOD TO	1 1100 0 0 2/ 2 1 / 2 0		

	ase 1:01-cv-12257-PBS I					<u> 20</u>	FIIE	<u>.u v.</u>	<u> </u>	10	<u>Fa</u>			
No		Qu	estion	/An	swer							. (Code	Sc2.2
Q10	How important are the following haemophilia A patients? Please important and 10 equals "extrement and 10 equals "extrement."	use	a 10 Impoi	point					equa		t at a	LÌ	i	
		port:								port		24	•	
	Recombinant vs human plasma-derived	1	2	3	4	5	6	7	8	9	0	٧	,18 	
	Well-established/standard product	1	2	3	4	5	6	7	8	9	0	V	1 *€	
	Albumin/protein content	1	2	3	4	5	6	7	8	9	0	٧	120	
	Efficacy/response rates	1	2	3	4	5	6	7	8	9	0	\	2	
	Duration of effect/half-life	1	2	3	4	5	6	7	8	9	0	٧	22.	
	Speed of response/effect	1	2	3	4	5	6	7	8	9	0	٧	(23	
	Safety (unspecified)	1	2	3	4	5	6	7	8	9	0	٧	24	
	Lack of adverse reactions	1	2	3	4	5	6	7	8	9	0	٧	25	
	Lack of albumin reaction	1	2	3	4	5	6	7	8	9	C	٧	26	
	Lack of (viral) contamination	1	2	3	4	5	6	7	8	9	0	٧	2~	
	Lack of immunity/resistance/ inhibitor development	1	2	3	4	5	6	7	8	9	0	٧	23	
	Range of potencies/vial sizes	1	2	3	4	5	6	7	8	9	0	٧	29 1	
	Diluent/infusion volume	1	2	3	4	5	6	7	8	9	0	٧	30	
	Storage (refingeration vs room temperature)	1	2	3	4	5	6	7	8	9	0	v'	, 0	
	Shelf-life	1	2	3	4	5	6	7	8	9	0	V	32	
	Supply/availability	1	2	3	4	5	6	7	8	9	С	•	33	
	Delivery to patient's home	1	2	3	4	5	6	7	8	9	0	٧	34	
	Manufacturer (i e reputation/ involvement in haemophilia)	1	2	3	4	5	6	7	8	9	C	٧	হে	
	Good relationship with manufacturer	1	2	3	4	5	6	7	8	9	0	V	C5	
	Ease of reconstitution	1	2	3	. 4	5	6	7	8	9	0	٧	3~	
	Speed of reconstitution	1	2	3	4	. 5	6	7	8	Э	0	٧	CS	
	Ease of administration	1	2	3	4	5	6	7	8	9	0	٧	; 3 9	•
	Cost	1	2	3	4	5	6	7	8	9	0	V.	/40	
Q11	How satisfied are you with the c products? Would you say you w			allab	le rec	ombi	nant l	Facto	r VIII					
	SHOW CARD 1											(41	ł	
	Very dissatisf ed								4					
	Fairly dissatisfied								2					
				1	Neith	er sa	usied	i nor	dissat	sfied		3	!	ł
								Faii	ty sat	usfied		4		
}								Ve	ry sat	isfied	1	5		
									Don't	know	'	٧	•	
L	l													

No	Question / Answer	Code	Skip to
Q12	What improvements would you like to see made to recombinant Factor VIII products?		
	PROBE FULLY	(42)	
	Reduced use of albumin/protein	1	
	Improved efficac _i /response	2	
	Longer lasting effect/longer half-life	3	
	Improved speed of response/effect	4	
	Improved safety (unspecified)	5	
	Fewer adverse reactions	6	
	Reduced/no album n reaction	7	
	Reduced/no (viral) con amination	8	
	Reduced mmunity/resistance/inhibitor de /elopment	9	
	Higher potencies/large vial sizes	0	
		(43)	
	Reduced volume of diluent/infusion	1	
	Indication for continuous sinfusion	2	
	Improved storage (refingeration no required)	3	
	Longer shelf-life	4	
	Improved supply/availability	5	
	Clearer storage ir structions	6	
	Improved packaging/less wastage of ancillan products	7	
	Improved/easier reconstitution	8	
	Faster reconstitution	9	
	Improved/easier adm nistration	0	
	Reduced cost	X	
		(44)	
		(45)	
		(46)	
	1	(47)	
	Other (please specify)	X	1
		V 2	
	Don't know	V	l

No	Question / Answer	Code '	Skp *5
	HAND NURSE SHOW CARD A		
	THIS CARD LISTS SEVERAL FEATURES ON WHICH POTENTIAL NEW RECOMBINANT PRODUCTS FOR HAEMOPHILIA A MIGHT DIFFER PLEASE TAKE A FEW MINUTES TO READ OVER THE FEATURES AND THEIR VARIOUS LEVELS, AS THIS INFORMATION WILL MAKE THE FOLLOWING EXERCISE RUN MORE SMOOTHLY		
	ALLOW TIME TO READ ALL INFORMATION ON THE CARD		
	I HAVE HERE 32 CARDS, EACH DESCRIBING A POTENTIAL RECOMBINANT FACTOR VIII PRODUCT WITH A UNIQUE COMBINATION OF FEATURES NO TWO CARDS ARE EXACTLY THE SAME FOR THE PURPOSE OF THIS EXERCISE, PLEASE IMAGINE THAT THESE 32 POTENTIAL PRODUCTS ARE THE ONLY ONES AVAILABLE FOR THE TREATMENT OF HAEMOPHILIA A		
	HAND NURSE SHUFFLED CARDS		
	CONSIDERING YOUR PATIENTS WITH HAEMOPHILIA A, PLEASE SORT THESE 32 POTENTIAL PRODUCTS INTO 3 PILES ACCOPDING TO YOUR INTEREST IN USING THEM ONE PILE SHOULD CONTAIN THOSE PRODUCTS THAT YOU WOULD BE MOST INTERESTED IN USING, ONE THOSE PRODUCTS THAT YOU MIGHT CONSIDER USING AND ONE THOSE PRODUCTS THAT YOU WOULD BE LEAST INTERESTED IN USING YOU CAN HAVE ANY NUMBER OF CARDS NEACH OF THE 3 PILES	1	
	ASSUME THESE PRODUCTS ARE EQUAL ON ANY FEATURES THAT ARE NOT INCLUDED ON THE CARDS		
	THIS IS A VERY IMPORTANT PART OF THE STUDY PLEASE TAKE YOUR TIME AS WE REALISE THIS TASK REQUIRES CAREFUL CONSIDERATION	ı	
	WAIT UNTIL THE NURSE HAS SORTED ALL THE CARDS INTO THREE PILES THEN CONTINUE		•
	I WOULD NOW LIKE YOU TO RANK THESE 32 CARDS FROM TOP TO BOTTO !! STARTING WITH THE PRODUCT YOU ARE MOST INTERESTED IN USING FOR HAEMOPHILIA ON THE TOP, THROUGH TO THE PRODUCT YOU ARE LEAST INTERESTED IN USING ON THE BOTTOM	ı	
	PLEASE BEGIN BY RANKING THESE PRODUCTS IN THE "MOST INTERESTED" PILE.		
	AFTER "MOST INTERESTED" PILE IS RANKED, ASK THE NURSE TO CONTINUE WITH THE PILE OF PRODUCTS HE/SHE "MIGHT USE" AND THEN FINALLY RANK THE "LEAST INTERESTED" PILE.		
	ONCE THE NURSE HAS FINISHED SAY		
	PLEASE READ OUT THE NUMBERS OF THE CARDS IN THE ORDER YOU HAVE ARRANGED THEM. THE FIRST NUMBER YOU READ OUT SHOULD BE THE PRODUCT YOU ARE MOST INTERESTED IN USING AND THE LAST NUMBER YOU READ OUT SHOULD BE THE PRODUCT YOU ARE LEAST INTERESTED IN USING	 	
	RECORD RESPONSES ON NEXT PAGE		-

			(1)-(2)	(3)–(11)
TE IN EACH NUMBER	IN THE APPROPRIATE CO	LUMN BELOW	13	REPEAT
RANK	PRODUCT CARD	RANK	PRODUCT	
	NUMBER (12) (13)		CARD NUMBE (44) (45)	H
1 /MOST LUZZI VA	(12) (13)	47	(44) (45)	٦
1 (MOST LIKELY)	40 45	, 17	(40) (47)	Ĺ
•	(14) (15)	40	(46) (47)	7
2	40 40	. 18		_
	(16) (17)		(48) (49)	٦
3		19		1
•	(18) (19)		(50) (51)	-
4		20		•
	(20) (21)		(52) (53)	-
5		21]
	(22) (23)		(54) (55)	_
6		22		7
_	(24) (25)		(56) (57)	3
7		23	(-, (-,	1
•	(26) (27)	20	(58) (59)	
8		24	(5) (6)	7
	(28) (29)		(60) (61)	J
9		25		7
	(30) (31)		(62) (63)	<u>.</u>
10		26		7
	(32) (33)	25	(64) (65)	J
44	(02) (00)	07	(04) (00)	7
11		27		J
	(34) (35)		(66) (67)	_
12		28]
	(36) (37)		(68) (69)	
13		29		7
10	(20)	23		٠ د
	(38) (39)	,	(70) (71)	7
14	(40)	30		_
4=	(40) (41)	04	(72) (73)	٦
15	(49) (49)	31	774) 775)	1
	(42) (43)	20 /LEACT LIVELY	(74) (75)	٦
16		32 (LEAST LIKELY)		ل

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No.	Question / Answer	Ccce	Skp p
Q13	Considering the potential product that you ranked as the one you would be most interested in using, what are your reasons for ranking it first? PROBE FULLY		
		(76ı	
	·	(77)	-
		(78)	
Q14	Considering the potential product that you ranked as the one you would be	N-VIII-	
	most likely to use, how interested would you be in using it in the haemophilia A patients treated at this centre? Would you say you were		
	SHOW CARD 2	(79)	
	Not at all interested	1	1
	Not very interested	2	
	Neither interested nor disinterested	3	•
	Fairly interested	4	
	Very interested	5	
	Don't know	V	

THANK AND CLOSE

Version 3 (Final) 23rd November 1999

		. •		
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J. RECKNER ASSOCIATES - 99-1.531

RECOMBINANT FACTOR VIII POSITIONING STUDY NURSE QUESTIONNAIRE - USA

RESPONDENT SIGNATUR (signature)		NTERVIEWER SIGNATUS (signature) HE TERMS OUTLINE) BYTHE MRS CODE O	
Spanning alouer	DE FOR EEE	OUO (80) 1 2 3 4 5 6 7	8 9 O X V
TIME FINISHED	INTERVIEWED BY		75) (76) (77) (78) (79)
TIME STARTED	DATE OF INTERV	/IEW 9 9	(71) (72) (73) (74) OUO
		COLUMNS (22)-(64	
CA,OR,WA	9		
AZ,CO,ID,MT,NV,NM,UT,WY	8		
AR,LA,OK,TX	7	Don't know	V
AL,KY,MS,TN	6		(21)
DE,DC,FL,GA,MD,NC,SC,VA,WV	5		
IA,KS,MN,MO,NE,ND,SD	4	(17) (18) (19) (20)
IL,IN,MI,OH,WI	3	HOSPITAL BED SIZE	
NJ,NY,PA	2	,	
CT,ME,MA,NH,VT,RI	1	Non teaching	2
REGIONS	(14)	Teachng	i
			(16)
1 9		Priv₂ te not for profit	2
(12) (13)		Private for profit	1
YEAR OF QUALIFICATION		TYPE OF HOSPITAL	(15)
POST CODE TEL NO			(PRINT)
			- -
CENTRE NAME ADDRESS			(PRINT) (PRINT)
NAME			(PRINT)

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	· · · · · · · · · · · · · · · · · · ·	10	
		10	FEPE.
No	Question / Answer	Code	Srp p
Q1	Approximately how many haemophilia patients in total are treated at this centre?		
	(12) (13) (14)		
	<u> </u>	,15	
	Don't know	V	
Q2	Of all haemophiha patients treated at this centre, what percentage have		
	haemophilia A and what percentage have haemophilia B?		
	ı) Haemophilia A		
	(16) (17) (18)		
•	(10) (11) (10)	(9)	
	Don't know I	y y	
		V	
	n) Haemophilia B		
	(20) (21) (22)	(23)	
	% None	0	
	Don't know		
	RESPONDENT MUST HAVE HAEMOPHILIA A PATIENTS (SEE		
	SCREENER) ENSURE TOTAL EQUALS 100%		
	ENSURE TOTAL EQUALS 100%		
	EXPLAIN TO THE RESPONDENT THAT THE REST OF THE		
	QUESTIONNAIRE CONCENTRATES EXCLUSIVELY ON HAEMOPHILIA A		
Q3	Thinking of all the haemophilia A patients treated at this centre, what percentage		
	are adults and what percentage are paediatrics?		
	i) Adults		
	(24) (35) (26)	12 m	
	(24) (35) None	0	
·	Don't know	V	
	ii) Paediatrics	•	
	(28) (29) (30)	(31)	
	(26) (29) (30) None	3,	
	Don't know		
	ENSURE TOTAL EQUALS 100%		

Case 1:01-cv-12257-PBS Document 6866-20 Filed 01/27/10 Page 57 of 150 Question / Answer Code Skip to Q4 Thinking of all the haemophilia A patients treated at this centre, what percentage are mild, what percentage are moderate and what percentage are severe? ı) Mıld (35)None 0 Don't know II) Moderate (37)(36)(39)None 0 V Don't know nii) Severe (40)(41)(43)None 0 Don't know **ENSURE TOTAL EQUALS 100%** Q5 Thinking of all the haemophilia A patients treated at this centre, what percentage currently use recombinant Factor VIII products and what percentage use human plasma denved Factor VIII products? i) Recombinant (45)(46)(44)(47)Jon't know il) Human plasma (49)(48)None Don't know RESPONDENT MUST HAVE PATIENTS ON RECOMBINANT PRODUCTS (SEE SCREENER) **ENSURE TOTAL EQUALS 100%** Q6 Approximately how many haemophilia A patients do you see in a typical week? (53)L'on't know

Typically on how many occasions per week do you reconstitute/administer

RESPONDENT MUST BE INVOLVED IN THE RECONSTITUTION ADMINISTRATION OF RECOMBINANT PRODUCTS (SEE SCREENER)

occasions per week

Don't know

recombinant Factor VIII products?

(56)

(57)

Q7

(51) O V	
(55) V	
(59) V	
Pa	ge 3 of 11
	GH0014

8 00 0 No Question / Answer Code | Which specific brands of Factor VIII products are currently used in patients at this Q8a centre (both recombinant and human plasma derived products)? Q8b What percentage of the patients currently use (product from Q8a) ASK FOR EACH BRAND NAMED AT Q8a **ENSURE TOTAL EQUALS 100%** Q8a Q8b Usage Percentage of patients Recombinant (12)(18)7 0% 20 **Bioclate** Don't krow (22)Helixate 2 24, Don't know (26)(28. Kogenate 3 Don't krow (30)32 Recombinate 4 Dontkrow ' (34)(35)Refacto 5 0% 38 Don't knov ١. Human plasma (13) 1 (38)(39)c' 43 **Alphanate** Don" krow CCLU1**\S 4* -8 5_-^\^ (49)(50)(51)% 52 7 Humate-P Don't krow (54),58 Hemofil M 9 % Don't know ! ٧ (58)(E3) ٧ % Koate DVI **,** Don't krow (14) 2 (62)54 1 % Monarc M ₹ Don't kron £3) Monoclate-P 3 % Don't know (70)% (25) Other (specify) Don't know ٧ % 176 Don't krow

		(1)–(2) 12	(3)-(11) REPEAT
No	Question / Answer	Code	Skip to
Q9	What factors influence the choice of Factor VIII treatment for haemophilia A patients?		
•	PROBE FULLY	(12)	
	Recombinant vs human plasma-denved	1	
	Well-established/standard product	2	
	Albumin/pro*ein content	3	
	Efficacy/response rates	4	
	Duration of ef ect/half life	5	
	Speed of response/effect	6	
	Safety (unspecified)	7	
	Lack of adverse reactions	8	
	Lack of album in reaction	9	
	Lack of (viral) cor tamination	0	
	Lack of immunity/resistance/lack of inhibitor development	X	
	Range of potencies/vial sizes	V	
		(13)	
:	Diluent/infus on volume	1	
	Storage (refingeration vs room te nperature)	2	
i	Shelf-life	3	
	Supply/availability	4	
	Delivery to patient's home	5	
	Manufacturer (e g reputation/involvement in haemophilia)	6	
	(Good) relationship with the manufacturer	7	
	Ease of reconstitution	8	
	Speed of reconstitution	9	}
	Ease of administration	0	
	Cost	x	
		(14)	
	·	(15)	
	,	(16)	-
		(17)	1
	Other (please specify)	×	
	Don't know	v	

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	ase 1:01-cv-12257-PBS					-20	FIII	eu o	1/27	/10	Га	ge 6	0 01	100_0
No		Qu	estion	n/An	swer							C	cce	Subb
Q10	How important are the following haemophilia A patients? Please important" and 10 equals "extrement of the following had been supported by the following had been been been been been been been bee	use	a 10 impo	point	rating				equa		t a ' a],		
	ım	port	ant							porte		⊃K ¦		
	Recombinant vs human plasma-derived	1	2	3	4	5	6	7	8	9	0	?	2	
	Well-established/standard product	1	2	3	4	5	6	7	8	9	0	,	9	
	Albumin/protein content	1	2	3	4	5	6	7	8	9	0	٧.	20	
1	Efficacy/response rates	1	2	3	4	5	6	7	8	9	0	V 1	2*	
	Duration of effect/half-life	1	2	3	4	5	6	7	8	9	0	٧	22	
1	Speed of response/effect	4	2	3	4	5	6	7	ğ	ĝ	0	٧	20	
	Safety (unspecified)	1	2	3	4	5	6	7	8	9	0	٠,	24	
	Lack of adverse reactions	1	2	3	4	5	6	7	8	9	C	,	25	
	Lack of albumin reaction	1	2	3	4	5	6	7	8	9	0	ν,	28	
ŀ	Lack of (viral) contamination	1	2	3	4	5	6	7	8	9	C	v	27	
	Lack of immunity/resistance/ inhibitor development	1	2	3	4	5	6	7	8	9	0	٧	28	
	Range of potencies/vial sizes	1	2	3	4	5	6	7	8	9	0	٧	29	
	Diluent/infusion volume	1	2	3	4	5	6	7	8	9	0	•	30	
	Storage (refingeration vs room temperature)	1	2	3	4	5	6	7	8	9	0	٧	5	
ł	Shelf-life	1	2	3	4	5	6	7	8	9	0	J	C2	
	Supply/availability	1	2	3	4	5	6	7	8	9	0	V	23	
1	Delivery to patient's home	1	2	3	4	5	6	7	8	9	0	۱۷	34	
	Manufacturer (i e reputation/ involvement in haemophilia)	1	2	3	4	5	6	7	8	9	0	\ /	25	
	Good relationship with manufacturer	1	2	3	4	5	6	7	8	9	С	٧	S 8	
İ	Ease of reconstitution	1	2	3	4	5	6	7	8	9	0	ν,	3~	
	Speed of reconstitution	1	2	3	4	5	6	7	8	9	0	V 1	38	
	Ease of administration	· 1	2	3	4	5	6	7	8	9	0	٧	39	
	Cost	1	2	3	4	5	6	7	8	9	0	٧	40	
Q11	How satisfied are you with the coproducts? Would you say you w	urrer vere	ntiy av	railab	ie rec	ombi	nant i	Facto	r VIII					
1	SHOW CARD 1											(41		
}							١	/ery o	dissat	ısfied		1		
							F	airly o	dissat	shed		2		
•				1	Neith	er sat	sfied	nor c	dissat	ısfıed		3		l i
			*					Fair	ty sat	ısfied		4		
								Ve	ry sat	sfied	1	5		
								I	Don't	know	i	У		
											<u>i </u>			

No	Question / Answer	Code	Skip to
Q12	What improvements would you like to see made to recombinant Factor VIII products?		
	PROBE FULLY	(42)	
	Reduced use of albumin/protein	1	
	Improved efficac //response	2	
	Longer lasting effect/longer half-life	3	
	Improved speed of response/effect	4	
	Improved safety (u rspecified)	5	
	Fewer adverse reactions	6	
	Reduced/no album n reaction	7	
	Reduced/no (viral) con amination	8	<u>[</u>
	Reduced immunity/resistance/inhibitor de /elopment	9	
	Higher potencies/large vial sizes	0	
		(43)	
	Reduced volume of diluent/infusion	1	
	Indication for continuous infusion	2	 -
	Improved storage (refngeration no required)	3	
	Longer shelf-life	4	
	Improved supply/availability	5	
	· Clearer storage ir structions	6	
	Improved packaging/less wastage of ancillar products	7	
	Improved/easier rec onstitution	8	
	Faster reconstitution	9	
	Improved/easier administration	0	
	Recuced cost	×	
	·	(44)	1
	,	(45)	
:		(46)	
		(47)	
	Other (please specify)	X	-
	Don't know	V	ľ

No	Question / Answer	Code	Skp :
	HAND NURSE SHOW CARD A		
	THIS CARD LISTS SEVERAL FEATURES ON WHICH POTENTIAL NEW RECOMBINANT PRODUCTS FOR HAEMOPHILIA A MIGHT DIFFER PLEASE TAKE A FEW MINUTES TO READ OVER THE FEATURES AND THEIR VARIOUS LEVELS, AS THIS INFORMATION WILL MAKE THE FOLLOWING EXERCISE RUN MORE SMOOTHLY		
	ALLOW TIME TO READ ALL INFORMATION ON THE CARD		
٠	I HAVE HERE 32 CARDS, EACH DESCRIBING A POTENTIAL RECOMB NANT FACTOR VIII PRODUCT WITH A UNIQUE COMB.NATION OF FEATURES \C TWO CARDS ARE EXACTLY THE SAME FOR THE PURPOSE OF THIS EXERCISE, PLEASE IMAGINE THAT THESE 32 POTENTIAL PRODUCTS ARE THE ONLY ONES AVAILABLE FOR THE TREATMENT OF HAEMOPHILIA A		
	HAND NURSE SHUFFLED CARDS		
	CONSIDERING YOUR PATIENTS WITH HAEMOPHILIA A, PLEASE SORT THESE 32 POTENTIAL PRODUCTS INTO 3 PILES ACCORDING TO YOUR INTEREST IN USING THEM ONE PILE SHOULD CONTAIN THOSE PRODUCTS THAT YOU WOULD BE MOST INTERESTED IN USING, ONE THOSE PRODUCTS THAT YOU MIGHT CONSIDER USING AND ONE THOSE PRODUCTS THAT YOU WOULD BE LEAST INTERESTED IN USING YOU CAN HAVE ANY NUMBER OF CARDS IN EACH OF THE 3 PILES		
	ASSUME THESE PRODUCTS ARE EQUAL ON ANY FEATURES THAT ARE NOT INCLUDED ON THE CARDS		
	THIS IS A VERY IMPORTANT PART OF THE STUDY PLEASE TAKE YOUR TIVE AS WE REALISE THIS TASK REQUIRES CAREFUL CONSIDERATION		
	WAIT UNTIL THE NURSE HAS SORTED ALL THE CARDS INTO THREE PILES, THEN CONTINUE		
	I WOULD NOW LIKE YOU TO RANK THESE 32 CARDS FROM TOP TO BOTTOM, STARTING WITH THE PRODUCT YOU ARE MOST INTERESTED IN USING FOR HAEMOPHILIA ON THE TOP, THROUGH TO THE PRODUCT YOU ARE LEAST INTERESTED IN USING ON THE BOTTOM		
	PLEASE BEGIN BY RANKING THESE PRODUCTS IN THE "MOST INTERESTED" PILE		
	AFTER "MOST INTERESTED" PILE IS RANKED, ASK THE NURSE TO CONTINUE WITH THE PILE OF PRODUCTS HE/SHE "MIGHT USE" AND THEN FINALLY RANK THE "LEAST INTERESTED" PILE.		
	ONCE THE NURSE HAS FINISHED SAY.		
	PLEASE READ OUT THE NUMBERS OF THE CARDS IN THE ORDER YOU HAVE ARRANGED THEM THE FIRST NUMBER YOU READ OUT SHOULD BE THE PRODUCT YOU ARE MOST INTERESTED IN USING AND THE LAST NUMBER YOU READ OUT SHOULD BE THE PRODUCT YOU ARE LEAST INTERESTED IN USING		
	RECORD RESPONSES ON NEXT PAGE		

	IN THE APPROPRIATE CO	LOINT BLLOW	
RANK	PRODUCT CARD NUMBER	RANK	PRODUCT CARD NUMBER
	(12) (13)		(44) (45)
1 (MOST LIKELY)		17	
	(14) (15)		(46) (47)
2		18	
	(16) (17)		(48) (49)
3		19	
	(18) (19)		(50) (51)
4		20	
,	(20) (21)	20	(50) (50)
	(20) (21)		(52) (53)
5		21	
	(22) (23)		(54) (55)
6		22	
	(24) (25)		(56) (57)
7		23	
	(26) (27)		(58) (59)
8		24	
	(28) (29)		(60) (61)
9		25	
	(30) (31)		(62) (63)
10		26	
	(32) (33)		(64) (65)
11		27	
-	(34) (35)		(66) (67)
		, 00	(-, (-,
12		28	
	(36) (37)		(68) (69)
13		29	,
	(38) (39)		(70) (71)
14		30	
- •	(40) (41)		(72) (73)
15		31	
	(42) (43)		(74) (75)
16		32 (LEAST LIKELY)	

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No	Question / Answer	Code	8 00 0
Q13	Considering the potential product that you ranked as the one you would be most interested in using, what are your reasons for ranking it first? PROBE FULLY		
		178	
		(77	-
		<i>i</i> 78	•
Q14	Considering the potential product that you ranked as the one you would be most likely to use, how interested would you be in using it in the haemophilia A patients treated at this centre? Would you say you were		
·	SHOW CARD 2	(79	
	Not at all interested	ŧ	
ĺ	Not very interested	2	
	Neither interested nor disinterested	3	
	Fairly interested	4	
	Very interested	5	
	Don't know	\	,

		(1)-(2) 18	(3)-(11) REPEAT
No	Question / Answer	Code	Skip to
Q15	Considering the potential product that you ranked as the one you would be most likely to use, would you be willing to advocate paying a price premium for that product?	(12)	
	Yes	1	Q16 .
	No.	2	THANK
	Don't know	٧	AND CLOSE
Q16	What percentage price increase over currently available recombinant products would you consider to be acceptable?		
	(13) (14) (15) Depends	(16) X	Q17
	enter percentage Don't know GO TO Q17 IF 'DEPENDS', OTHERWISE THANK AND CLOSE	v	THANK AND CLOSE
Q17	On what would the acceptable level of price increase depend? PROBE FULLY		
		(17)	
		(18)	
		(19)	
	_		

THANK AND CLOSE

Version 3 (Final) 23rd November 1999

	-, -, -	. ago oo	<u> </u>	
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CC	V No	Country	Senal	Nur

INTERNATIONAL HEALTH SURVEYS, LUDGATE HOUSE, 245 BLACKFRIARS ROAD, LONDON SE1 9UL

RECOMBINANT FACTOR VIII POSITIONING STUDY NURSE QUESTIONNAIRE — <u>JAPAI</u>

THIS INTERVIEW	(signature) / HAS BEEN CONDUCTED WITHIN THE T	ERMS OUTLINED BYTHE	signature) MRS CODE	OF CONDUCT
RESPONDE	ENT SIGNATURE FOR FEE.	INTERVIE	WER SIGNATI	JRE
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		7	Oon't know	(21) V
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-		1C	PERE-
No	Question / Answer	Coce	Sec :
Q1	Approximately how many haemophilia patients in total are treated at this centre?		
	400 400		
	(12) (13) (14)		
		15:	
	Don't know	٧	
Q2	Of all haemophilia patients treated at this centre, what percentage have		
O(La	haemophilia A and what percentage have haemophilia B?		
	N Hannata a		
	i) Haemophilia A		
	(16) (17) (18) %	(4.0)	
1	i — — — — — — — — — — — — — — — — — — —	119 1	
	Don't know ii) Haemophilia B	٧	
		00	
	(20) (21) (22)	23 O	
	% None		
	Don't know	V	
	RESPONDENT MUST HAVE HAEMOPHILIA A PATIENTS (SEE SCREENER)		
	ENSURE TOTAL EQUALS 100%		
	EXPLAIN TO THE RESPONDENT THAT THE REST OF THE QUESTIONNAIRE CONCENTRATES EXCLUSIVELY ON HAEMOPHILIA A		•
Q3	Thinking of all the haemophilia A patients treated at this centre, what percentage		
	are adults and what percentage are paediatrics?		
	i) Adults		
	(24) (25) (26)	(27)	
	% None	0	
	Don't know	`,	
	ii) Paediatrics		
	(28) (29) (30)	31	
	None None	C	
	Don't know } ENSURE TOTAL EQUALS 100%	٧	

Case 1:01-cv-12257-PBS Document 6866-20 Filed 01/27/10 Page 68 of 150 No Question / Answer Code Skip to Q4 Thinking of all the haemophilia A patients treated at this centre, what percentage are mild, what percentage are moderate and what percentage are severe? i) Mild (33)(34)(35)None 0 Jon't know ii) Moderate (36)(37)(39)None 0 Don't know ni) Severe (40)(41)(43)None 0 Don't know **ENSURE TOTAL EQUALS 100%** Q5 Thinking of all the haemophilia A patients treated at this centre, what percentage currently use recombinant Factor VIII products and what percentage use human plasma derived Factor VIII products? i) Recombinant (44)(45)(46)(47)Don't know il) Human plasma (49)(50)(51)None E on't know RESPONDENT MUST HAVE PATIENTS ON RECOMBINANT PRODUCTS (SEE SCREENER) **ENSURE TOTAL EQUALS 100%** Approximately how many haemophilia A patients do you see in a typical week? Q6 (52)(53)(54)(55)**E'on't know Q7** Typically on how many occasions per week do you reconstitute/administer recombinant Factor VIII products? (57)(58)occasions per week (59)Don't know RESPONDENT MUST BE INVOLVED IN THE RECONSTITUTION ADMINISTRATION OF RECOMBINANT PRODUCTS (SEE SCREENER)

(1)-(2 11 No Question / Answer Code Sec c Q8a Which specific brands of Factor VIII products are currently used in patients at this centre (both recombinant and human plasma derived products)? Q8b What percentage of the patients currently use (product from Q8a ASK FOR EACH BRAND NAMED AT Q8a **ENSURE TOTAL EQUALS 100%** Q8a Q8b Usage Percentage of patients COLUMNS 17-24 BL-14 Recombinant (12)(25)(26)(27)Kogenate 3 % 128 Don't know (29)(30)(31)Recombinate 32 Don't know COLUMNS 33 - 40 BLANK Human plasma (13)1 % 3 Contact F Don't know o'e -8 Crosseight M (50)(51)(49)1 % 7 52 Haemate P Don't know ١, (53)(54)(55)56, Haemofil M 9 Don't know COLUMNS 5TH 88 BLANK **COLUMN (14) BLANK** (15)(69)Other (specify) X % 72 Don't know (16)X 176 ٧ Don't know

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		(1)–(2) 12	(3)-(11) REPEAT
No	Question / Answer	Code	Skip to
Q9	What factors influence the choice of Factor VIII treatment for haemo shiha A		
	patients?		1
	PROBE FULLY	(12)	
i	Recombinant vs human p as na-derived	1	
	Well-established/standard product	2	
	Albumin/protein content	3	
	Efficacy/response rates	4	İ
	Duration of eff act/half life	5	
	Speed of response/effect	6	
	Safety (u specified)	7	Ì
	Lack of adverse reactions	8	
	Lack of album n reaction	9	
	Lack of (viral) con amination	0	
	Lack of immunity/resistance/lack of inhibitor de /elopment	X	
	Range of potencier-Avial sizes	V	
	·	(13)	
	Diluent/infusion volume	1	
	Storage (refngeration vs room *ernperature)	2	
	Shelf-life Shelf-life	3	
	Supply/availability	4	
	Delivery to patic nt's home	5	
	Manufacturer (e.g. reputation/involvement in ha emophilia)	6	
	(Good) relationship with the manufacturer	7	
	Ease of reconstitution	8	
	Speed of reconstitution	9	
	Ease of adm inistration	0	ļ
	Cost	x	
		(14)	
	·	(15)	_
		(16)	-
		(17)	1
	Other (please specify)	x	
	C on't know	v	

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	ور البران المستون المناز والمناز		

No		Qu	estion	/An	swer								cae	\$<: :
Q10	How important are the following haemophilia A patients? Please important and 10 equals extrem	use	a 10	point								11		
	No	t at a	ali							treme porta		25		
-	Recombinant vs human plasma-derived	1	2	3	4	5	6	7	8	9	0	. V	\$	
	Well-established/standard product	1	2	3	4	5	6	7	8	9	0	V	.9	
	Albumin/protein content	1	2	3	4	5	6	7	8	9	0	V	20	
	Efficacy/response rates	1	2	3	4	5	6	7	8	9	0	ν,	2	
	Duration of effect/half-life	1	2	3	4	5	6	7	8	9	0	γ	22	
	Speed of response/effect	1	2	3	4	5	6	7	8	9	0	٧	20	
	Safety (unspecified)	1	2	3	4	5	6	7	8	9	C	٧	24	
	Lack of adverse reactions	1	2	3	4	5	6	7	8	9	0	V	25	
	Lack of albumin reaction	1	2	3	4	5	6	7	8	9	0	V	125	
	Lack of (viral) contamination	1	2	3	4	5	6	7	8	9	0	ν	2~	
•	Lack of immunity/resistance/ inhibitor development	1	2	3	4	5	6	7	8	9	0	✓ ;	28	
	Range of potencies/vial sizes	1	2	3	4	5	6	7	8	9	Э	*	29	
	Diluent/infusion volume	1	2	3	4	5	6	7	8	9	0	٧	30	
	Storage (refngeration vs room temperature)	1	2	3	4	5	6	7	8	9	0	V	3	
	Shelf-life	1	2	3	4	5	6	7	8	9	0	W	22	
	Supply/availability	1	2	3	4	5	6	7	8	9	C	V	CC	
	Delivery to patient's home	1	2	3	4	5	6	7	8	9	0	17	34	
	Manufacturer (i e reputation/ involvement in haemophilia)	1	2	3	4	5	6	7	8	9	0	٧	55	
	Good relationship with manufacturer	1	2	3	4	5	6	7	8 ,	9	С	٧	26	
	Ease of reconstitution	1	2	3	4	5	6	7	8	9	0	٧	:37	
!	Speed of reconstitution	1	2	3	4	5	6	7	8	9	C	٧	38	
	Ease of administration	1	2	3	4	5	6	7	8	9,	C	٧	39	
	Cost	1	2	3	4	5	6	7	8	9	၁		40	
Q11	How satisfied are you with the c products? Would you say you w		ntly av	ailab	le rec	eombi	nant l	Facto	r VIII					
	SHOW CARD 1											(41	}	
	:							-	dissati			•		
	1							_	dissati		1	2		
					Neith	er sat	sfied		dissa*		1	3		
مو	·								ly sat		1	4		
									ry sat		1	5		
								1	Don't	know		٧		

No	Question / Answer	Code	Skip to
Q12	What improvements would you like to see made to recombinan' Factor VIII products'?		
	PROBE FULLY	(42)	
	Reduced use of albumin/protein	1	
	Improved effica zy/response	2	
	Longer lasting effect/lor ger half-life	3	
	Improved speed of response/effect	4	
	Improved safety (unspecified)	5	
	Fewer adver e reactions	6	
	Reduced/no alburnin reaction	7	
	Reduced/no (viral) contamination	8	
	Reduced immunity/resistance/inhibitor development	9	
	Higher potencies/larger vial sizes	0	
		(43)	
	Reduced volume of chluent/infusion	1	
	Indication for continuous infusion	2	
	Improved storage (refingeration not required)	3	
	Longer shelf-life	4	
	Improved supply availability	5	
	Clearer storage instructions	6	
	Improved packaging/less wastage of ancilla y products	7	
	Improved/easier reconstitution	8	
	Faster reconstitution	. 9	
	Improved/easier adr inistration	0	
	Reduced cost	×	
		(44)	
		(45)	
		(46)	,
		(47)	
	Other (please specify)	×	

	Don't know	V	

No	Question / Answer	Code	S == 0 1	
	HAND NURSE SHOW CARD A			
	THIS CARD LISTS SEVERAL FEATURES ON WHICH POTENTIAL NEW . RECOMBINANT PRODUCTS FOR HAEMOPHILIA A MIGHT DIFFER. PLEASE ! TAKE A FEW MINUTES TO READ OVER THE FEATURES AND THEIR VARICLS ! LEVELS, AS THIS INFORMATION WILL MAKE THE FOLLOWING EXERCISE PLIN MORE SMOOTHLY		ı	
	ALLOW TIME TO READ ALL INFORMATION ON THE CARD			
	I HAVE HERE 32 CARDS, EACH DESCRIBING A POTENTIAL RECOMBINANT! FACTOR VIII PRODUCT WITH A UNIQUE COMBINATION OF FEATURES NO TWO CARDS ARE EXACTLY THE SAME. FOR THE PURPOSE OF THIS EXERCISE, PLEASE IMAGINE THAT THESE 32 POTENTIAL PRODUCTS ARE THE ONLY ONES AVAILABLE FOR THE TREATMENT OF HAEMOPHILIA A.			
	HAND NURSE SHUFFLED CARDS			
	CONSIDERING YOUR PATIENTS WITH HAEMOPHILIA A, PLEASE SORT THESE 32 POTENTIAL PRODUCTS INTO 3 PILES ACCORDING TO YOUR INTEREST IN USING THEM ONE PILE SHOULD CONTAIN THOSE PRODUCTS THAT YOU WOULD BE MOST INTERESTED IN USING, ONE THOSE PRODUCTS THAT YOU MIGHT CONSIDER USING AND ONE THOSE PRODUCTS THAT YOU WOULD BE LEAST INTERESTED IN USING YOU CAN HAVE ANY NUMBER OF CARDS IN EACH OF THE 3 PILES			
	ASSUME THESE PRODUCTS ARE EQUAL ON ANY FEATURES THAT ARE NOT INCLUDED ON THE CARDS			
	THIS IS A VERY IMPORTANT PART OF THE STUDY PLEASE TAKE YOUR TIME AS WE REALISE THIS TASK REQUIRES CAREFUL CONSIDERATION			
	WAIT UNTIL THE NURSE HAS SORTED ALL THE CARDS INTO THREE PILES THEN CONTINUE			
•	I WOULD NOW LIKE YOU TO RANK THESE 32 CARDS FROM TOP TO BOTTO 'STARTING WITH THE PRODUCT YOU ARE MOST INTERESTED IN USING FOR HAEMOPHILIA ON THE TOP, THROUGH TO THE PRODUCT YOU ARE LEAST INTERESTED IN USING ON THE BOTTOM			
	PLEASE BEGIN BY RANKING THESE PRODUCTS IN THE "MOST INTERESTED" PILE			
	AFTER "MOST INTERESTED" PILE IS RANKED, ASK THE NURSE TO CONTINUE WITH THE PILE OF PRODUCTS HE/SHE "MIGHT USE" AND THEN FINALLY RANK THE "LEAST INTERESTED" PILE.			
	ONCE THE NURSE HAS FINISHED SAY			
	PLEASE READ OUT THE NUMBERS OF THE CARDS IN THE ORDER YOU HAVE ARRANGED THEM THE FIRST NUMBER YOU READ OUT SHOULD BE THE PRODUCT YOU ARE MOST INTERESTED IN USING AND THE LAST NUMBER YOU READ OUT SHOULD BE THE PRODUCT YOU ARE LEAST INTERESTED IN USING			
	RECORD RESPONSES ON NEXT PAGE			

			(1)-(2) (3)-(11) 13 REPEAT
'E IN EACH NUMBER RANK	IN THE APPROPRIATE CO	DLUMN BELOW RANK	PRODUCT
MANN	NUMBER	nank T	CARD NUMBER
	(12) (13)		(44) (45)
1 (MOST LIKELY)		17	
	(14) (15)		(46) (47)
2		18	
	(16) (17)		(48) (49)
3		19	
	(18) (19)		(50) (51)
4		20	
	(20) (21)	{	(52) (53)
5		21	
	(22) (23)		(54) (55)
6	(32) (33)	22	(0-1) (00)
Ü	(24) (25)		(56) (57)
7	(24) (23)	23	(00) (01)
•	(26) (27)	۵	(58) (59)
8		24	(00) (03)
J	(28) (29)		(60) (61)
9		25	
·	(30) (31)		(62) (63)
40	(00) (01)	00	(02) (03)
10	(20) (20)	26	(61) (67)
	(32) (33)		(64) (65)
11		27	,
	(34) (35)		(66) (67)
12		28	•
	(36) (37)		(68) (69)
40		90	()
13		29	
	(38) (39)		(70) (71)
14		30	
	(40) (41)		(72) (73)
15		31	
	(42) (43)		(74) (75)
16		32 (LEAST LIKELY)	

No_	ase 1:01-cv-12257-PBS Document 6866-20 Filed 01/27/10 Question / Answer	Page 75 of 150
Q13	Considering the potential product that you ranked as the one you would be most interested in using, what are your reasons for ranking it first? PROBE FULLY	
		(76)
		(78)
Q14	Considering the potential product that you ranked as the one you would be most likely to use, how interested would you be in using it in the haemophilia A patients treated at this centre? Would you say you were	
	SHOW CARD 2	(79)
	Not at all interested	∢
	Not very interested	2
	Neither interested nor disinterested	3
	Fairly interested	4
	Very interested	5
	Don't know	V

CARD A

Nurses

Human or animal derived protein

- > used in manufacturing (culturing) and in he final formulation (for stabilising)
- > used in manufacturing (culturing), but not in the final formulation (for stabilising)
- > not used at all

Continuous infusion

- > an approved indication
- > product has capability, but not approved (label indication)
- > not possible (to be used for continuous infusior)

Diluent volume per vial

- > 25ml
- > 5ml
- > 10ml

Higher number of activity units per vial

- > 1,000 i u per vial
- > 1,250 i.u per vial
- > 1,500 ru per vial
- > 2,000 i u per vial

Assay issue

- > requires one-stage assay
- > requires chromogenic assay (not available in every hospital)

Room temperature storage

- > Cannot be stored at room temperature (requires refingeration)
- > 3 months
- ➤ 6 months
- ➤ 1 year
- > 2+ years

Reconstitution

- > current standard (two vials) with transfer needles
- > current standard, with needleless reconstitution/mixing
- > single step procedure (i e pre-filled, ready-to-use syringe)

NURSE - CARD 1

Human or animal derived protein

> used in manufacturing (culturing) and in the final formulation (for stabilising)

Continuous infusion

> product has capability, but not approved (label indication)

Diluent volume per vial
> 10ml

Higher number of activity units per vial

> 1,500 i u per vial

Assay issue

> requires one-stage assay

Room temperature storage

> 1 year

Reconstitution

> single step procedure (i e pre-filled, ready-to-use syringe)

NURSE - CARD 2

Human or animal derived protein

> used in manufacturing (culturing) and in the final formulation (for stables = g

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 5ml

Higher number of activity units per vial

> 1,250 ı u per vial

Assay Issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage

≥ 2+ years

Reconstitution

NURSE - CARD 3

Human or animal derived protein

> nct used at all

Continuous infusion

> an approved indication

Diluent volume per vial

> 10ml

Higher number of activity units per vial

> 2,000 i u per vial

Assay issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage

> Cannot be stored at room temperature (requires refingeration)

Reconstitution

NURSE - CARD 4

Human or animal derived protein > not used at all

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial > 5mt

Higher number of activity units per vial

> 1,000 ru per vial

Assay issue

> requires one-stage assay

Room temperature storage

▶ 6 months

Reconstitution

NURSE - CARD 5

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stabilising)

Continuous infusion

> product has capability, but not approved (label indication)

Diluent volume per vial

> 10ml

Higher number of activity units per vial

> 2,000 ru per vial

Assay Issue

> requires one-stage assay

Room temperature storage

> 2+ years

Reconstitution

NURSE - CARD 6

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation iter stables no

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 5ml

Higher number of activity units per vial

> 1,000 i u per vial

Assay Issue

> required chromogenic assay (not available in every hospital)

Room temperature storage

➤ 1 year

Reconstitution

NURSE - CARD 7

Human or animal derived protein

➤ not used at all

Continuous infusion

➤ an approved indication

Diluent volume per vial
➤ 10ml

Assay issue

> requires chromogenic assay (not available in ever / hospital)

Room temperature storage > 6 months

Reconstitution

NURSE - CARD 8

Human or animal derived protein

➤ not used at all

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 5ml

Higher number of activity units per vial > 1,250 ι u per vial

Assay issue

> requires one-stage assay

Room temperature storage

> Cannot be stored at room temperature (requires refingeration)

Reconstitution

> single step procedure (i e pre-filled, ready-to-use synnge)

NURSE - CARD 9

Human or animal derived protein

> used in manufacturing (culturing) and in the final formulation (for stabilising)

Continuous infusion

> product has capability, but not approved (label indication)

Diluent volume per vial

> 25ml

Higher number of activity units per vial

> 1,250 i u per vial

Assay Issue

> requires one-stage assay

Room temperature storage

➤ 6 months

Reconstitution

NURSE - CARD 10

Human or animal derived protein

> used in manufacturing (culturing) and in the final formulation (for stabilising)

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 5ml

Higher number of activity units per vial > 1,500 i u. per vial

Assay Issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage

> Cannot be stored at room temperature (requires refingeration)

Reconstitution

NURSE - CARD 11

Human or animal derived protein

➤ not used at all

Continuous infusion

➤ an approved indication

Diluent volume per vial

> 2 5ml

Higher number of activity units per vial

> 1,000 i u per vial

Assay issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage

> 2+ years

Reconstitution

> single step procedure (i e pre-filled, ready-to-use synnge)

NURSE - CARD 12

Human or animal derived protein

> not used at all

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 5m!

Higher number of activity units per vial > 2,000 ι u. per vial

Assay Issue

> requires one-stage assay

Room temperature storage

> 1 year

Reconstitution

NURSE - CARD 13

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stabilising)

Continuous infusion

> product has capability, but not approved (label indication)

Diluent volume per vial

> 2.5ml

Higher number of activity units per vial

> 1,000 i u per vial

Assay issue

> requires one-stage assay

Room temperature storage

> Cannot be stored at room temperature (requires reingeration)

Reconstitution

NURSE - CARD 14

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stabilising

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 5mi

Higher number of activity units per vial

> 2,000 i u pervial

Assay issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage

> 6 months

Reconstitution

> single step procedure (i e pre-filled, ready-to-use synnge)

NURSE - CARD 15

Human or animal derived protein

➤ not used at all

Continuous infusion

> an approved indication

Diluent volume per vial ➤ 25ml

Higher number of activity units per vial > 1,250 i u per vial

Assay Issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage

> 1 year

Reconstitution

NURSE - CARD 16

Human or animal derived protein

➤ not used at all

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 5ml

Higher number of activity units per vial

> 1,500 i u per vial

Assay issue

> requires one-stage assay

Room temperature storage

> 2+ years

Reconstitution

NURSE - CARD 17

Human or animal derived protein > not used at all

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 2.5ml

Higher number of activity units per vial

> 1,500 ru per vial

Assay issue

> recluires one-stage assay

Room temperature storage

> 3 months

Reconstitution

NURSE - CARD 18

Human or animal derived protein

➤ not used at all

Continuous infusion

> product has capability, but not approved (label indication)

Diluent volume per vial

> 5ml

Higher number of activity units per vial ➤ 1,250 u per vial

Assay Issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage
➤ 2+ years

Reconstitution

NURSE - CARD 20

Human or animal derived protein

> used in manufacturing (culturing) and in the final formulation (for stabilising,

Continuous infusion

> an approved indication

Diluent volume per vial

> 5ml

Higher number of activity units per vial

> 1,000 i u per vial

Assay issue

> requires one-stage assay

Room temperature storage

> 6 months

Reconstitution

> single step procedure (i e pre-filled, ready-to-use synnge)

NURSE - CARD 21

Human or animal derived protein

> not used at all

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 2 5ml

Higher number of activity units per vial

> 2,000 u per vial

Assay issue

> requires one-stage assay

Room temperature storage

> 2+ years

Reconstitution

> single step procedure (i e pre-filled, ready-to-use s /nnge)

NURSE - CARD 22

Human or animal derived protein

➤ not used at all

Continuous infusion

> product has capability, but not approved (label indication)

Diluent volume per vial

> 5ml

Higher number of activity units per vial

> 1,000 ru per vial

Assay issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage

> 3 months

Reconstitution

NURSE - CARD 23

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stabilising)

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial
➤ 2 5ml

Higher number of activity units per vial > 1,500 i u per vial

Assay issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage
➤ 6 months

Reconstitution

NURSE - CARD 24

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stabilising

Continuous infusion

> an approved indication

Diluent volume per vial

> 5mi

Higher number of activity units per vial

> 1,250 i u per viai

Assay Issue

> requires one-stage assay

Room temperature storage

> Cannot be stored at room temperature (requires refingeration)

Reconstitution

NURSE - CARD 25

Human or animal derived protein

> not used at all

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 10ml

Higher number of activity units per vial

> 1,250 i u per vial

Assay Issue

> requires one-stage assay

Room temperature storage
➤ 6 months

Reconstitution

NURSE - CARD 26

Human or animal derived protein > not used at all

Continuous infusion

> product has capability, but not approved (label indication)

Diluent volume per vial ➤ 5ml

Higher number of activity units per vial

➤ 1,500 i u per vial

Assay issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage

> Cannot be stored at room temperature (requires refingeration)

Reconstitution

> single step procedure (i e pre-filled, ready-to-use synnge)

NURSE - CARD 27

Human or animal derived protein

> used in manufacturing (culturing) and in the final formulation (for stabilising)

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 10ml

Higher number of activity units per vial

> 1,000 ru per vial

Assay issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage

> 2+ years

Reconstitution

NURSE - CARD 28

Human or animal derived protein

> used in manufacturing (culturing) and in the final formulation (for stab ising

Continuous infusion

> an approved indication

Diluent volume per vial

> 5ml

Higher number of activity units per vial

> 2,000 i u pervial

Assay issue

> requires one-stage assay

Room temperature storage
➤ 3 months

Reconstitution

NURSE - CARD 29

Human or animal derived protein

> not used at all

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 10ml

Higher number of activity units per vial

> 1,000 i u per vial

Assay issue

> recluires one-stage assay

Room temperature storage

> Cannot be stored at room temperature (requires refigeration)

Reconstitution

NURSE - CARD 30

Human or animal derived protein

> not used at all

Continuous infusion

> product has capability, but not approved (label indication)

Diluent volume per vial

> 5ml

Higher number of activity units per vial

> 2,000 i u per vial

Assay issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage

> 6 months

Reconstitution

NURSE - CARD 31

Human or animal derived protein

> used in manufacturing (culturing), but not in the fir al formulation (for stabilising)

Continuous infusion

> not possible (to be used for continuous infusion)

Diluent volume per vial

> 10ml

Higher number of activity units per vial

> 1,250 i u per vial

Assay Issue

> requires chromogenic assay (not available in every hospital)

Room temperature storage

⇒ 3 months

Reconstitution

> single step procedure (i e pre-filled, ready-to-use synnge)

NURSE - CARD 32

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stapling)

Continuous infusion

> an approved indication

Diluent volume per vial

> 5ml

Higher number of activity units per vial

> 1,500 ru per vial

Assay Issue

> requires one-stage assay

Room temperature storage

≥ 2+ years

Reconstitution

Appendix I

(c) Patients

J500398 Version 2 (Final)

110-11	147 147	1 10	(0) - (10)	(4)
14	0398			3
CC	V No	Country	Sensi	Pt.

INTERNATIONAL HEALTH SURVEYS, LUDGATE HOUSE, 245 BLACKFRIARS ROAD, LONDON SE1 9UL

RECOMBINANT FVIII POSITIONING STUDY PATIENT SCREENING QUESTIONN AIRE

Patient name	
Address	
(please pnnt)	
····	
Telephona No	Additional grant grant grant grant contract of the contract of

INTRODUCTION

GOOD MORNING/AFTERNOON MY NAME IS FROM INTERNATIONAL HEALTH SURVEYS, AN INDEPENDENT MARKET RESEARCH AGENCY BASED IN LONDON, WHICH SPECIALISE IN CONDUCTING SURVEYS AMONG MEMBERS OF THE MEDICAL PROFE SSION AND PATIENTS

WE ARE CURRENTLY CONDUCTING AN INTERNATIONAL STUDY WITH DOCTORS, NURSES AND PATIENTS ON THE SUBJECT OF HAEMOPHILIA A

YOUR NAME HAS BEEN GIVEN TO US BY

THE INTERVIEW WILL LAST UP TO 45 MINUTES THE INFORMATION YOU PROVIDE WILL BE COMBINED WITH THAT OF CTHER PATIENTS YOUR IDENTIFY WILL NOT BE REVEALED TO ANY THIRD PARTY STRICT CONFIDENTIALITY IS ASSURED

WOULD YOU BE WILLING TO TAKE PART IN OUR SURVEY?

COULD I FIRST ASK YOU A FEW QUESTIONS TO ASSESS YOUR ELIGIEILITY FOR THIS SURVEY

No	Question / Answer	Code	Skip to
Q1	Could I begin by confirming whether you personally suffer from haemophilia A or whether you have a child who suffers from the condition?	(12)	
}	Respondent per onally	1	
	Child	2	
	PROCEED ACCORDING TO QUOTAS		
Q2	Do you/does your child currently use a <u>recombinant</u> Factor VIII product to treat the haemophilia A (e.g. Helixate, Kogenate, Recombinate or Refecto)?		
	ADAPT PRODUCTS ACCORDING TO COUNTRY	(13)	
	Yes	1	RECRUIT
1	No	2	THANK &
	Don't know	V	CLOSE

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23 ^m November 1999		C V No	Country	Senal	Pł

INTERNATIONAL HEALTH SURVEYS, LUDGATE HOUSE, 245 BLACKFRIARS ROAD, LONDON SE1 9UL

RECOMBINANT FACTOR VIII POSITIONING STUDY PATIENT QUESTIONNAIRE

NAME ADDRESS			(PRINT) (PRINT)
POST CODE TEL NO			(PRINT)
RESPONDENT TYPE		REGION (UK VERSION)	
	(12)	•	(17)
Haemophilia sufferer	1	Scotland	1
Parent of child with haemophilia	2	Tyne Tees	2
		Granada	3
AGE (OF CHILD, if appropriate)		Yorkshire	4
(13) (14)	ì	Central	5
years	(15)	Harlech	6
Refused	X	Anglia	7
		Cariton/LWT	8
SOCIAL CLASS (UK VERSION)	(16)	Mendian	9
A	1	West Country TV	0
В	2		
C1	3		
C2	4		
D	5		
E	6		
Refused	X		
c		COLUMNS (18)-(6	34) BLANK
TIME STARTED	DATE OF INTERVIEW	(65) (66) (67 (68) (69) (70) 9 9	(71) (72) (73) (74)
TIME FINISHED	INTERVIEWED BY		(75) (76) (77) (78) (79)
		O (80) 1 2 3 4 5 6 7	8 9 0 X V
RESPONDENT SIGNATURE F	UH FEB	INTERVIEWER SIGNATU	JNE.
(s gnature) THIS INTERVIEW HAS BEEN CON	DUCTED WITHIN THE T	(signature) ERMS OUTLINED 3YTHE MRS CODE	OF CONDUCT

Case 1:01-cv-12257-PBS Document 6866-20 Filed 01/27/10 Page 111 of 150 No Question / Answer Code Sec : Q1 How long ago is it since you were/your child was diagnosed with haemophilia RECORD AS YEARS OR MONTHS (12)(13)(14)(15)months QR years (15) Less than 1 month X V Don't know For how long have you/has your child been using a recombinant Factor VIII **Q2** product? RECORD AS YEARS OR MONTHS (19)(20)(17)(18)years <u>OR</u> months (21 Less than 1 month | Х ٧ Don't know **ENSURE LESS THAN EQUAL TO ANSWER TO Q1** Do you/does your child currently take Factor VIII regularly as Q3 prophylaxis/prevention or do you/does your child on take it only on an as needed basis? (22 Regu ar prophylaxis/prevention As needed 2 **'23** X Other (please specify) Don't know ٧ **Q4** Do you/does your child have a catheter (Portacath) for the administration of the Factor VIII?

,24

2

٧

Yes

No

Don't know

Cas	e 1:01-cv-12257-PBS Document 6866-	20 Filed	01/2	7/10 Pag	je 112 of 150 Code Skip to				
Q5a	Which specific brand of Factor VIII products are you	u/is your chik	curre						
	RESPONDENT/CHILD MUST BE USING A RECO! SCREENER)	MBINANT PR	ODUC	T (SEE					
	RECORD IN APPROPRIATE COLUMN BELOW								
Q5b	Which, if any, other brand(s) of Factor VIII have you	ı/has your ch	ıld ıse	d in the past	,				
	RECORD IN APPROPRIATE COLUMN BELOW	-		-					
		Q5a		Q5b					
		Currently		Past	,				
	Recombinant	(25)		(27)					
	Bioclate	1		.1					
	Helocate	2		2					
·	Kogenate	3		3					
	Recombinate	4	,	4					
	Refacto	5		5					
	(ONLY FOR Q5b) Human plasma			(28)					
	Alphanate	1		1					
	Benate :		 1	2					
	Contact F			3					
	Crosseight M			4					
	Emoclot			5					
	Fhandi			6					
	Haemate-P/Humate P			7	į				
	Haemoctin SDH Hemofil M			8 9	,				
	Immunate			0					
	innobrand			x					
	Koate DVI			٧					
			1	(29)					
	Kryobulin			1					
	Monarc M		'	2	į				
	Monoclate-P			3	,				
	Nordiate			4					
	Octenate Octinativ M			5					
	Profilate		ĺ	6 7					
ļ	Replenate		1	8					
	Uman		(9					
		(26)	[]	(30)					
	Others (please specify)	×	İ	×					
	Q5a								
~	Q5b	•	•						
·	(ONLY FOR Q5b) No other brand used in past		[0					
	Don't know	ν.		٧					

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Q6a	How satisfied are you with your/your child's current recombinant Factor VIII treatment? Would you say you were		
	SHOW CARD 1	(31)	I
	Very dissatisfied	1	
	Fairly dissatisfied	2	Q85
	Neither satisfied nor dissatisfied	3	
	Fairly satisfied	4	
	Very satisfied	5	Q8:
	Don't know	V	37
Q6b	Why do you say you are dissatisfied with your/your child's current recombinant Factor VIII treatment?		
	PROBE FULLY		
		32	
		(33)	
		· · · · · · · · · · · · · · · · · · ·	
		341	
		!	
			<u> </u>
Q6c	Why do you say you are satisfied with your/your child's current recombinant Factor VIII treatment?	1	
	PROBE FULLY		
		351	
			•
		351	
		i !	
		' "3	
			<u> </u>

140	e 1:01-cv-12257-PBS Document 6866-20 Filed 01/27/10 F	age 114 of Code	150 Skip to
Q 7	What factors influence your choice of Factor VIII treatment for haemophilia A?		1
	PROBE FULLY	(3B)]
	Recombinant vs human plasma-derived	1	
	Albumin/prctein content	2	
	Efficacy/response rates	3	ļ
	Duration of effect/half life	4	
	Speed of rest onse/effect	5	
	Safety (unspecified)	6	
	Lack of adverse reactions	7	1
	Lack of (viral) contamination	8	
	Range of potencies/vial sizes	9	
	·	(39)	ļ
	Diluent/irfus on volume	1	
	Storage (refingeration vs room te inperature)	2	
	Shelf-life	3	
	Delivery to patient's home	4	
	Ease of reconstitution	5	
	Speed of reconstitution	6	
ı	Ease of adr inistration	7	
	Cost	8	j
		(40)	
		7,43	
		(41)	
		(42)	
		(43)	
	Other (please specify)	X	
		~	
	Have no influence on choice of product	0	
	Don't know	v	

No	ase 1:01-cv-12257-Pl	BS Document 6866-20 Filed 01/27 Question / Answer	/10	Page 115 of	8k2 :
18	What improvements wou products?	ald you like to see made to recombinant Factor	or VIII	(44)	
	PROBE FULLY	Reduced use of protein/all	חותשכ	•	
		Improved efficacy/resp	ponse	2	
		Longer lasting effect/longer has	alf-life	3	
		Improved speed of response/	effect	4	
		Improved safety (unspec	ofied)	5	
	,	Fewer adverse read	ctions	6	
		Reduced/no (viral) contamir	ration	-	
		Higher potencies/larger vial	sizes	8	
		Reduced volume of diluent/inf	usion	Э	
				(45)	
		Improved storage (refingeration not requ	uıred)		
		Longer she	elf-lrfe	2	
		Clearer storage instruc	ctions	3	
	fr	nproved packaging/less wastage of ancillary pro-	ducts	4	
		Improved/easier reconstr	tution	. 5	
	1	Faster reconstri	tution	6	
		Improved/easier administr	ration	7	•
		Reduces	ರ್ ೧೦೩	3	•
		·		1 78	
				14-	
				1 22	
				(48)	
				-49	
		Other (please spe	еспу)	×	
				_	
	1	Don't	know	\ \	

	e 1:01-cv-12257-PBS Document 6866-20 Filed 01/27/10 Page		
140	HAND PATIENT SHOW CARD A	Code	Skip to
	THIS CARD LISTS SEVERAL FEATURES ON WHICH POTENTIAL NEW RECOMBINANT PRODUCTS FOR HAEMOPHILIA A MIGHT D FFER PLEASE TAKE A FEW MINUTES TO READ OVER THE FEATURES AND THEIR VARIOUS LEVELS, AS THIS INFORMATION WILL MAKE THE FOLLOWING EXERCISE RUN MORE SMOOTHLY	-	
	ALLOW RESPONDENT TIME TO READ ALL INFORMATION ON THE CARD		
	I HAVE HERE 25 CARDS, EACH DESCRIBING A POTENTIAL RECOMBINANT FACTOR VIII PRODUCT WITH A UNIQUE COMBINATION OF FEATURES NO TWO CARDS ARE EXACTLY THE SAME FOR THE PURPOSE OF THIS EXERCISE, PLEASE IMAGINE THAT THESE 25 POTENTIAL PRODUCTS ARE THE ONLY ONES AVAILABLE FOR THE TREATMENT OF HAEMOPHIL A A		
	HAND PATIENT SHUFFLED CARDS		
	PLEASE SORT THESE 25 POTENTIAL PRODUCTS INTO 3 PILES ACCORDING TO YOUR INTEREST IN USE OF THEM ONE PILE SHOULD CONTAIN THOSE PRODUCTS THAT YOU WOULD BE MOST INTERESTED IN USING, ONE THOSE PRODUCTS THAT YOU MIGHT CONSIDER USING AND ONE THOSE PRODUCTS THAT YOU WOULD BE LEAST INTERESTED IN USING YOU CAN HAVE ANY NUMBER OF CARDS IN EACH OF THE 3 PILES		
	ASSUME THESE PRODUCTS ARE EQUAL ON ANY FEATURES THAT ARE NOT INCLUDED ON THE CARDS		
İ	THIS IS A VERY IMPORTANT PART OF THE STUDY PLEASE TAKE YOUR TIME AS WE REALISE THIS TASK REQUIRES CAREFUL CONSIDERATION		1
į	WAIT UNTIL THE PATIENT HAS SORTED ALL THE CARDS INTO THREE PILES, THEN CONTINUE		• :
	I WOULD NOW LIKE YOU TO RANK THESE 25 CARDS FROM TO? TO BOTTOM, STARTING WITH THE PRODUCT YOU ARE MOST INTERESTED IN THE TOP, THROUGH TO THE PRODUCT YOU ARE LEAST INTERESTED IN USING ON THE BOTTOM		
	PLEASE BEGIN BY RANKING THESE PRODUCTS IN THE "MOST INTERESTED" PILE		
	AFTER "MOST INTERESTED" PILE IS RANKED, ASK THE PATIENT TO CONTINUE WITH THE PILE OF PRODUCTS HE/SHE "MIGHT USE" AND THEN FINALLY RANK THE "LEAST INTERESTED" PILE.		
	ONCE THE PATIENT HAS FINISHED SAY:		
	PLEASE READ OUT THE NUMBERS OF THE CARDS IN THE ORD ER YOU HAVE ARRANGED THEM THE FIRST NUMBER YOU READ OUT SHOULD BE THE PRODUCT YOU ARE MOST INTERESTED IN USING AND THE LAST NUMBER YOU READ OUT SHOULD BE THE PRODUCT YOU ARE LEAST INTERESTED IN USING		
	RECORD RESPONSES ON NEXT PAGE		
	,		

RANK	PRODUCT CARD	RANK	PRODUCT
	NUMBER (12)		CARD NUMBER (44) '451
4 / 100 00 1 1 4 7 1 4	(12) (13)	47	(44) '451
1 (MOST LIKELY)		17	<u></u>
	(14) (15)		(46) (47)
2		18	
	(16) (17)	•	(48) 149
3		19	
	(18) (19)		(50) 51
4		20	
	(20) (21)		(52) (53,
5		21	
5		21	
_	(22) (23)		(54) 55
. 6		22	453
	(24) (25)		(56) 57
7		23	
_	(26) (27)	24	(58) 59
8	(00) (00)	24	(60) 61
	(28) (29)	or	(60) 8°
9		25 .	<u> </u>
	(30) (31)		
10			•
	(32) (33)		
11			
	(34) (35)		
10			
12			
	(36) (37)		
13			
	(38) (39)		
14			
	(40) (41)		
15			•
•-	(42) (43)		
16			

טאו	Question / Answer	Code	Skip to
Q9	Considering the potential product that you ranked as the one you would be most interested in using, what are your reasons for ranking it first?		
	PROBE FULLY		
		(62)	
Ì		(UL)	
		(63)	
		(64)	
Q10	Considering the potential product that you ranked as the one you would be most likely to use, how interested would you be in using it (in your child)? Would you say you were		
į	SHOW CARD 2	(65)	
[Not at all interested	1	
	Not very interested	2	
	Neither interested nor disinterested	3	
	Fa rly nterested	4	•
	Very nterested	5	
	Don't know	v	
Q11-1	3 USA only		
Q11	Considering the potential product that you ranked as the one you would be		
	most likely to use, do you believe a price premium for that product would be acceptable?	(66)	
	Yes	1	Q12
1	No	2	THANK
	Don't know	v	AND CLOSE
		·	OLOGE
Q12	What percentage price increase over currently available recombinant products would you consider to be acceptable?		
	(67) (68) (69)	(70)	
	% Depends	×	Q13
	enter percentage Don't know	V	THANK
	GO TO Q13 IF 'DEPENDS', OTHERWISE THANK AND CLOSE		CLOSE
Q13	On what would the acceptable level of pnce increase depend?		
	PROBE FULLY	(71)	
1			} .
}		(72)	
1			
}	· ·		
}	,	(73)	
	,	(73)	

THANK AND CLOSE

CARD A .

Patients

Human or animal derived protein

- > used in manufacturing (culturing) and in the final formulation (for stabilising)
- > used in manufacturing (culturing), but not in the final formulation (for stabilising)
- > not used at all

Diluent volume per vial

- > 25ml
- > 5ml
- > 10ml

Higher number of activity units per vial

- > 1,000 iu pervial
- > 1,250 i u per vial
- > 1,500 i u per vial
- > 2,000 i u per vial

Room temperature storage

- > Cannot be stored at room temperature (requires refingeration)
- > 3 months
- > 6 months
- > 1 year
- > 2+ years

Reconstitution

- > current standard (two vials) with transfer needles
- > current standard, with needleless reconstitution/mixing
- > single step procedure (i e pre-filled, ready-to-use synnge)

PATIENT - CARD 1

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stabilising)

Diluent volume per vial

≥ 2 5ml

Higher number of activity units per vial > 2,000 i u per vial

Room temperature storage

> Cannot be stored at room temperature (requires refingeration)

Reconstitution

PATIENT - CARD 2

Human or animal derived protein

> used in manufacturing (culturing) and in the final formulation (for stables ng

Diluent volume per vial

> 25ml

Higher number of activity units per vial

> 1,500 i.u per vial

Room temperature storage

> 1 year

Reconstitution

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stabilising)

Diluent volume per vial

> 10ml

Higher number of activity units per vial

> 1,250 i u per vial

Room temperature storage

> 2+ years

Reconstitution

> current standard, with needleless reconstitution/mixing

PATIENT - CARD 4

Human or animal derived protein

> not used at all

Diluent volume per vial > 5ml

Higher number of activity units per vial ➤ 1,500 i u per vial

Room temperature storage

> Cannot be stored at room temperature (requires refingeration)

Reconstitution

> current standard, with needleless reconstitution/mixing

PATIENT - CARD 5

Human or animal derived protein

➤ not used at all

Diluent volume per vial

> 5ml

Higher number of activity units per vial > 1,000 i u per vial

Room temperature storage
➤ 6 months

Reconstitution

PATIENT - CARD 6

Human or animal derived protein

➤ not used at all

Diluent volume per vial
> 10ml

Higher number of activity units per vial > 2,000 i u per vial

Room temperature storage
➤ 1 year

Reconstitution

> single step procedure (i e pre-filled, ready-to-use synnge)

PATIENT - CARD 7

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stabilising)

Diluent volume per vial ➤ 25ml

Higher number of activity units per vial > 1,000 i u per vial

Room temperature storage
> 1 year

Reconstitution

> current standard, with needleless reconstitution/mixing

PATIENT - CARD 8

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stap 's ng

Diluent volume per vial

> 10ml

Higher number of activity units per vial

> 1,250 i u per vial

Room temperature storage

➤ Cannot be stored at room temperature (requires refingeration)

Reconstitution

> single step procedure (i e pre-filled, ready-to-use synnge)

PATIENT - CARD 9

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stabilising)

Diluent volume per vial
➤ 25ml

Higher number of activity units per vial ➤ 1,250 i u per vial

Room temperature storage

> 6 months

Reconstitution

> single step procedure (i e pre-filled, ready-to-use synnge)

PATIENT - CARD 10

Human or anımal derived protein

➤ not used at all

Diluent volume per vial

➤ 25ml

Higher number of activity units per vial ➤ 2,000 i u per vial

Room temperature storage
➤ 3 months

Reconstitution

> single step procedure (i e pre-filled, ready-to-use syringe)

PATIENT - CARD 11

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stabilising)

Diluent volume per vial

> 5ml

Higher number of activity units per vial

> 1,250 i u per vial

Room temperature storage

➤ 1 year

Reconstitution

> single step procedure (i.e. pre-filled, ready-to-use synnge)

PATIENT - CARD 12

Human or animal derived protein

➤ used in manufacturing (culturing), but not in the final formulation (for stap is ng

Diluent volume per vial
➤ 25ml

Higher number of activity units per vial

> 1,500 i u per vial

Room temperature storage
➤ 6 months

Reconstitution

> single step procedure (i e pre-filled, ready-to-use syringe)

PATIENT - CARD 13

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stabilising)

Diluent volume per vial > 10ml

Higher number of activity units per vial

> 1,000 tu per vial

Room temperature storage
➤ 3 months

Reconstitution

PATIENT - CARD 14

Human or animal derived protein

➤ not used at all

Diluent volume per vial > 10ml

Higher number of activity units per vial ➤ 1,250 i u per vial

Room temperature storage
➤ 6 months

Reconstitution

PATIENT - CARD 15

Human or animal derived protein

➤ not used at all

Diluent volume per vial > 25ml

Higher number of activity units per vial > 1,250 i u per vial

Room temperature storage

> Cannot be stored at room temperature (requires refigeration)

Reconstitution

PATIENT - CARD 16

Human or animal derived protein

➤ not used at all

Diluent volume per vial
> 2 5ml

Higher number of activity units per vial > 1,000 i u per vial

Room temperature storage
> 2+ years

Reconstitution

> single step procedure (i e pre-filled, ready-to-use synnge)

PATIENT - CARD 17

Human or animal derived protein

> used in manufacturing (culturing) and in the final formulation (for stabilising)

Diluent volume per vial

> 25ml

Higher number of activity units per vial > 1,250 i u per vial

Room temperature storage

> 2+ years

Reconstitution

PATIENT - CARD 18

Human or animal derived protein

> used in manufacturing (culturing) and in the final formulation (for stableing

Diluent volume per vial > 5ml

Higher number of activity units per vial

> 1,250 i u per vial

Room temperature storage
➤ 3 months

Reconstitution

> single step procedure (i e pre-filled, ready-to-use synnge)

PATIENT - CARD 19

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stabilising)

Diluent volume per vial

> 5ml

Higher number of activity units per vial

> 2,000 ru per vial

Room temperature storage

≥ 2+ years

Reconstitution

PATIENT - CARD 20

Human or animal derived protein

> used in manufacturing (culturing) and in the final formulation (for stab final

Diluent volume per vial
➤ 10ml

Higher number of activity units per vial

> 1,000 i u per vial

Room temperature storage

> Cannot be stored at room temperature (requires refingeration)

Reconstitution

> single step procedure

PATIENT - CARD 21

Human or animal derived protein

> used in manufacturing (culturing) and in the final formulation (for stabilising)

Diluent volume per vial

> 10ml

Higher number of activity units per vial > 2,000 i u per vial

Room temperature storage

> 6 months

Reconstitution

> current standard, with needleless reconstitution/mixing

PATIENT - CARD 22

Human or animal derived protein

➤ not used at all

Diluent volume per vial
> 10ml

Higher number of activity units per vial > 1,250 i u per vial

Room temperature storage

> 1 year

Reconstitution

PATIENT - CARD 23

Human or animal derived protein

➤ not used at all

Diluent volume per vial
> 10ml

Higher number of activity units per vial

> 1,500 i u per vial

Room temperature storage > 2+ years

Reconstitution

> single step procedure (i e pre-filled, ready-to-use s/mge)

PATIENT - CARD 24

Human or animal derived protein

> used in manufacturing (culturing), but not in the final formulation (for stables not stable not stab

PATIENT - CARD 25

Human or animal derived protein

➤ not used at all

Diluent volume per vial ≥ 25ml

Higher number of activity units per vial > 1,250 i u per vial

Room temperature storage > 3 months

Reconstitution

> current standard, with needleless reconstitution/mixing

Appendix II

Trade-off/conjoint

- (a) Attribute list
- (b) Statistical results
- (c) Background

500398 - Haemophilia

Attributes for conjoint

- 1 Human protein
 - i) used in manufacturing and stabiliting (final formulation)
 - used in manufacturing (culturing), but not in the final formulation (for stabilising)
 - III) not used at all
- 2 Continuous infusion
 - i) an approved indication
 - ii) product has capability, but not approved (label indication)
 - iii) not possible (to be used for continuous infusion)
- 3 Diluent volume
 - i) 25ml
 - n) 5ml
 - iii) 10ml
- 4 High potency
 - ı) 1,000 i u
 - ii) 1,250 i u
 - m) 1,500 i u
 - iv) 2,000 i u
- 5 Assay issue
 - i) requires one-stage assay
 - ii) requires chromogenic assay (not available in every hospital)
- 6 Room temperature storage
 - i) Cannot be stored at room 'emperature (requires refrigeration)
 - ii) 3 months
 - iii) 6 months
 - v) 1 year
 - v) 2+ years

7 Reconstitution

- i) current standard (two vials) with transfer needles
- ii) current standard, with needleless reconstitution mixing
- iii) single step procedure (i e pre-filled, ready-to-use surnge

8 rFViii molecule

- ı) full length
- ii) B-domain deleted

Doctors

- 1 Human protein
- 2 Continuous infusion
- 3 Diluent volume
- 4 High potency
- 5 Assay Issue
- 6 Room temperature storage
- 8 rFVIII molecule

Nurses

- 1 Human protein
- 2 Continuous infusion
- 3 Diluent volume
- 4 High potency
- 5 Assay Issue
- 6 Room temperature storage
- 7 Reconstitution

Patients

- 1 Human protein
- 3 Diluent volume
- 4 High potency
- 6 Room temperature storage
- 7 Reconstitution

J500398

Utility & Average Importances

Attributes	Doctors		Nurses		Patients	
	Mean	<u>se</u>	Mean	Se	<u>Mean</u>	\$e
1 Human protein	39%		34.4		45%	
Used in manufacturing and stabilising (final formulation)	8 0	03	0 fi	02	11	02
Used in manufacturing (culturing), but not in the final formulation (for stabilising)	41	04	42	05	27	03
Not used at all	112	06	10 2	08	9 1	04
2 Continuous infusion	26%		22%		0%	
An approved indication	73	05	6 €	07		
Product has capability, but not approved (label indication)	52	05	4 E	05		
Not possible (to be used for continuous infusion)	0 4	02	0 E	02		
3 Diluent volume	1%		7%		3%	
2 5ml	21	03	38	05	24	02
5ml	17	02	36	05	20	02
10ml	18	03	19	03	19	02
4 High potency	3%		5%		6%	
1,000 i u	18	02	1 4	03	20	02
1,250 เ ช	14	02	17	02	23	02
1,500 ւ ս	21	02	21	03	31	02
2,000 i u	16	02	28	04	28	02
5 Assay issue	11%		5%		0%	
Requires one-stage assay	34	04	24	04		
Requires chromogenic assay (not available in every hospital)	0.5	01	09	02		
6 Room temperature storage	19%		20%		34%	
Cannot be stored at room temperature (requires refingeration)	12	03	21	0 4	15	03
3 months	35	0.4	28	0.4	42	03
6 months	5 4	04	45	05	54	03
1 year	6 1	05	68	06	69	03
2+ years	62	05	77	07	76	04
7 Reconstitution	0%		7%		11%	
Current standard (two vials) with transfer needles			09	02	15	01
Current standard, with needleless reconstitution/mixing			21	03	21	02
Single step procedure (i e pre-filled, ready-to-use syringe)			29	05	34	02
8 rFVIII molecule	1%		0%		0%	
Full length	11	02				
B-domain deleted	09	02			· · · · · · · · · · · · · · · · · · ·	
Base	98		52		171	

'Trade-off / Conjoint analysis

1. Background

A common problem often encountered within the research arena is that of measuring the relative importance of attributes within a product. Trade-off analysis decomposes the product into a number of features or attributes. The respondents then trade-off these attributes against one another, forcing them to indicate their preferences. From this information, it is possible to es'ablish the relative importance of each of the attributes – thus providing a wealth of useful, clear information and powerful modelling capabilities.

2. Full profile conjoint

2.1 Methodology

A full profile conjoint technique is one whereby

- > each attribute is further broken down into different I evels,
- > product concepts are formed by combining different attribute levels,
- > respondents are presented with cards each containing different product concepts,
- > respondents are asked to rank the cards in order of preference

This forces respondents to trade-off all the attributes against one another at the same time

2.2 Analysis and utilities

The full profile conjoint technique produces rankings for attribute combinations Modelling techniques are then used to produce utilities or each level of each of the attributes. The utilities are measures of the value or attractiveness of each attribute level to respondents. They are calculated for each individual respondent. A measure of importance is also derived for each attribute. This shows how important the attribute is in the choice process. These are produced for the whole respondent set.

Baxter Hyland Immuno

The utilities are used to

- > identify the most popular options within an attribute the righer the right the more popular the option or level,
- > measure the importance of the attributes the distance between the most and least popular levels within an attribute dictate the attribute's importance
- > assess the value of different product combinations the utimes are acc = e

Having collected rankings on a small subset of all possible product concepts or combinations, we can calculate the relative preference for every cossible product combination. This is done by simply adding together the utilities of each of the attribute levels within a product concept.

These product utilities can be calculated on an individual respondent cas's.

can then be compared – the product with the highest utility will be the one that the respondent will prefer. Hence we can estimate market share for different chacks simulating the marketplace. We can fine-tune products to maximise market share or minimise cost whilst maintaining market share.